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Prejudicial Interpretation of Expert Reliability on the “Cutting Edge” Enables the Orthopaedic Implant Industry’s Bodily Eminent Domain Claim

Frank Griffin M.D.
University of Arkansas

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Prejudicial Interpretation of Expert Reliability on the “Cutting Edge” Enables the Orthopaedic Implant Industry’s Bodily Eminent Domain Claim

Frank Griffin, M.D., J.D.*

Failure of judicial gatekeepers to accurately assess reliability of expert witness testimony under Daubert in orthopaedic device defective design cases is creating an artificial and unreasonable barrier to recovery for a uniquely vulnerable patient population. Tendencies to ignore major conflicts of interest and overemphasize systematically biased epidemiology studies while excluding novel research in preparation for trial and personal experience experts give industry a decisive advantage. Consequently, the orthopaedic implant industry uses the less rigorous “substantial equivalence” pathway to orthopaedic device approval at markedly higher rates than non-orthopaedic medical devices, resulting in a much higher device recall rate with resultant costs to the public. Current judicial trends facilitate a kind of “bodily eminent domain” claim by industry resulting in an unnecessary and costly “taking” of Americans’ health.

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* The author is an orthopaedic surgeon and an adjunct professor at the University of Arkansas School of Law (beginning January 2017).

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“*Striving to better, oft we mar what’s well.*” William Shakespeare.¹

I. INTRODUCTION

The orthopaedic device industry has revolutionized the treatment of many musculoskeletal problems with devices from bone plates to total knee replacements restoring function and quality to patients’ lives. For example, over 90% of patients using any of several types of total hip or knee replacements placed in use by the 1980s had good or excellent outcomes lasting at least fifteen to twenty years.² Today, the orthopaedic device industry is a multibillion dollar industry generating over \$43 billion annually in worldwide revenues, with over 60% generated in the United States alone.³ As with any big

1. WILLIAM SHAKESPEARE, KING LEAR act 1, sc. 4 (Jay L. Halio ed., Cambridge Univ. Press updated ed. 2005).

2. See, e.g., David R. Diduch & John N. Insall et al., *Total Knee Replacement in Young, Active Patients: Long-Term Follow-Up and Functional Outcome*, 79A J. BONE & JOINT SURGERY AM. 575 (1997); Lars Neumann et al., *Long-Term Results of Charnley Total Hip Replacement: Review of 92 Patients at 15 to 20 Years*, 76B J. BONE & JOINT SURGERY BRIT. 245 (1994).

3. ORTHOKNOW, STRATEGIC INSIGHTS INTO THE ORTHOPAEDIC INDUSTRY 1 (2012). The top three orthopaedic device companies have market caps of JNJ

business, competitiveness and innovation are keys to maintaining or improving market share.⁴ From the latest iPhone to self-driving cars to the latest total knee replacement, Americans want the latest and greatest advancements.

But what happens when an “advancement” is not really an innovation or improvement at all? What if the enemy of “good” is “better,”⁵ and the new device has worse outcomes than its predecessor? What if the failed “advancement” is more of a marketing ploy with minimal scientific foundation advanced by a company to gain market share rather than to improve patient outcomes?

Orthopaedic device manufacturers may feel justified in taking liberties with patients’ health to stake claim to the “cutting edge” if the likelihood of negative business consequences is small.⁶ Some in medicine openly espouse the idea that it is okay to take liberties with patients’ health to benefit others; in order for medical students and residents to learn, some argue that it is necessary for young doctors to avoid disclosure of inexperience, in what is known as the “physician’s dodge.”⁷ A prominent physician author says, “[l]earning must be stolen, taken as a kind of *bodily eminent domain*.”⁸ But

\$293.3B, SYK \$38.44B, and ZBH \$19.93B. See *Johnson & Johnson*, N.Y. STOCK EXCH. (Mar. 3, 2016), <http://www.google.com/finance?q=NYSE:JNJ>.

4. See generally Peter W. Roberts, *Product Innovation, Product-Market Competition and Persistent Profitability in the U.S. Pharmaceutical Industry*, 20 STRAT. MGMT. J. 655 (1999) (outlining how strategy and innovation drive persistent profits in the pharmaceutical industry).

5. This is an English variant of Italian proverb popularized by Voltaire in the 1600s. See SUSAN RATCLIFFE, OXFORD CONCISE DICTIONARY OF QUOTATIONS 389 (6th ed. 2011).

6. See Tarek Salaway et al., *Technology in Surgery and the Future of Integrated Care*, INFECTION CONTROL & CLINICAL QUALITY (Feb. 24, 2016), <http://www.beckershospitalreview.com/quality/technology-in-surgery-and-the-future-of-integrated-care.html> (“The evolving technological sophistication of a hospital, and the degree to which that technology is perceived to enhance patient outcomes remains one of the key factors that attract patients to it and its programs.”); see also Andrew M. Seaman, *Adoption of New Surgical Technology Linked to Complications*, REUTERS (July 8, 2014, 2:53 PM), <http://www.reuters.com/article/us-surgery-devices-complications-idUSKBN0FD26T20140708> (“Patients may be more likely to have complications when a new surgical device is first being adopted, suggests a new study looking at prostate removal.”).

7. ATUL GAWANDE, COMPLICATIONS: A SURGEON’S NOTES ON AN IMPERFECT SCIENCE 32–33 (2002) (illustrating how the relative inexperience of a physician can be intentionally unspoken).

8. *Id.* at 32 (emphasis added).

should such a “bodily eminent domain” claim extend to the orthopaedic device industry?⁹

This paper explores the idea that current design defect law enables the orthopaedic device industry to stake an eminent domain-like claim on patients’ health in the United States.¹⁰ First, allegations by a prominent orthopaedic leader that the device industry is actually controlling orthopaedic medicine such that medicine is nothing more than a “marketing arm of industry” will be explored because, if true, the court system is facing a particularly vulnerable patient population worthy of judicial attention.¹¹ Second, the current application of design defect law to orthopaedic implant cases will be explored with particular attention to two total joint replacement devices recently in the news,¹² and prejudicial judicial tendencies that may embolden aggressive industry practices will be discussed. Finally, the desirability of the courts protecting a vulnerable population by shifting the risks associated with implant design decisions onto device manufacturers and away from doctors, patients, and society as a whole is explored.

II. WAG THE DOG: THE ORTHOPAEDIC IMPLANT INDUSTRY PRESENTS A UNIQUE PROBLEM FOR THE COURT SYSTEM

The orthopaedic device industry presents a unique problem to the courts because there is evidence that the industry may be controlling medicine—instead of vice versa. Orthopaedic surgery is heavily dependent upon the device industry. In 2003, Professor Augusto Sarmiento wrote that, “medicine has become a tool that functions primarily as a *marketing arm of industry*” with “patient welfare . . . little more than a desirable (*but not*

9. For an alternative viewpoint regarding physician disclosure obligations—discussing informed consent doctrine—see, e.g., *Lucas v. Awaad*, 830 N.W.2d 141, 150–51 (Mich. Ct. App. 2013).

10. Cf. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (AM. LAW INST. 1998). This paper is limited to a discussion of “defective in design” without consideration of manufacturing defects, failure to warn, or warranty issues.

11. AUGUSTO SARMIENTO, BARE BONES: A SURGEON’S TALE: THE PRICE OF SUCCESS IN AMERICAN MEDICINE 284 (2003).

12. The author does not assert that any of the devices mentioned in this paper are “defective in design”—that is a question only juries can decide, when informed properly by experts in the field.

essential) byproduct.”¹³ Sarmiento is a former president of the American Academy of Orthopaedic Surgeons (the “world’s largest medical association of musculoskeletal specialists” now with over 39,000 members worldwide)¹⁴ and former chairman of the Department of Orthopaedic Surgery at the University of Southern California. Sarmiento continued, “I feel comfortable in stating that the *education of today’s orthopedists is structured, to a great extent, to satisfy the marketing needs of industry.*”¹⁵ Sarmiento adds that orthopaedic residency students simply use the educational system to “learn to use industry’s tools.”¹⁶ The dependence of orthopaedic residents on industry representatives can be shocking, with one sales representative saying, “It sounds ridiculous, because here’s a guy who went to medical school and residency, and he’s listening to some guy in the back of the room.”¹⁷ Another sales rep added, “It’s not uncommon to have a surgeon with a drill in his hand, about to drill a hole, looking over his shoulder at you saying, ‘Is this right?’”¹⁸ The culture of orthopaedic surgeons may also play a role with orthopaedic surgeons having a reputation as “predominantly male” and the “jocks of the surgical world” with a particular willingness to use devices in “unapproved ways,”¹⁹ and likely, by extension, to use devices that are new rather than better.

Evidence that suggests that Sarmiento’s assessment that the industry “tail” is wagging the proverbial orthopaedic “dog” is accurate includes (A) signs of abuse or corruption including fines, settlements, and prison terms in the orthopaedic industry,²⁰ (B) unexplainable “striking shifts” away from proven devices to new devices with ultimately worse outcomes,²¹ and (C) disproportionate use of shortcut regulatory

13. SARMIENTO, *supra* note 11, at 284 (emphasis added).

14. *Background*, AM. ACAD. OF ORTHOPAEDIC SURGEONS, <http://www.aaos.org/CustomTemplates/Content.aspx?id=1604> (last visited Oct. 4, 2016).

15. SARMIENTO, *supra* note 11, at 284 (emphasis added).

16. *Id.*

17. Mina Kimes, *Bad to the Bone: A Medical Horror Story*, FORTUNE (Sept. 18, 2012, 9:00 AM), <http://fortune.com/2012/09/18/bad-to-the-bone-a-medical-horror-story>.

18. *Id.*

19. *Id.*

20. See the discussion *infra* Part II.A.

21. See the discussion *infra* Part II.B.

pathways to device clearance in spite of public outcry from respected voices demanding change.²²

A. SIGNS OF ABUSE/CORRUPTION IN THE INDUSTRY: DOJ FINES, SETTLEMENTS, AND PRISON

An environment of alleged kickbacks, settlements, “off-label” promotion, and prison sentences suggests that the orthopaedic device industry is willing to take liberties to control the marketplace for profit. In 2007, criminal complaints were settled against four orthopaedic implant companies alleging that they were paying surgeons to use their devices in violation of the federal anti-kickback laws.²³ A fifth company, Stryker®, cooperated with the investigation and was not included.²⁴ Those five companies together controlled 88% of the U.S. total joint replacement market.²⁵ Ultimately, the four companies settled with the Department of Justice for \$311 million in fines, including Zimmer® (\$170M), DePuy® (\$85M), Biomet® (\$27M), and Smith & Nephew® (\$29M).²⁶

Off-label promotion is another sign of companies’ eminent domain-like attitude toward patient health. In one case, four implant company executives served jail time after promoting unapproved off-label uses—even against explicit FDA instructions—that allegedly resulted in at least five patient deaths on the operating table.²⁷ If the profits from off-label promotion outweigh the fines, or outweigh the expense of clinical trials, companies may be making a calculated business decision at the expense of a few patients’ health (or deaths).²⁸

22. See the discussion *infra* Part II.C.

23. See Janice Hopkins Tanne, *U.S. Companies Are Fined for Payments to Surgeons*, 335 BRIT. MED. J. 1065 (2007); News Release, Christopher J. Christie, U.S. Att’y, Dist. of N.J., Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring (Sept. 27, 2007), <https://www.justice.gov/sites/default/files/usao-nj/legacy/2013/11/29/hips0927.rel.pdf>.

24. See News Release, Christie, *supra* note 23.

25. See *id.*; cf. ORTHOKNOW, *supra* note 3, at fig.2 (showing Depuy/JNJ having 23% of the market share, Biomet with 11%, Zimmer with 24%, Smith & Nephew with 12%, and Stryker with 18%).

26. See Tanne, *supra* note 23.

27. Kimes, *supra* note 17 (“The Food and Drug Administration explicitly told [the medical device company] not to promote [the product] for certain spine surgeries, but the company pushed forward anyway.”).

28. *Id.* (“Off-label marketing is so common among drug and device makers that it’s often dismissed as the equivalent of driving slightly over the speed

In the aforementioned case, a clinical trial would reportedly have cost about \$1 million for the off-label use, so the company instead devised a plan to “get a few sites to perform 60–80 procedures and help them publish their clinical results.”²⁹ The company reportedly hoped that having “a few doctors [perform] the procedure[s] on their own” without clinical trials would “popularize the product,” but instead it allegedly cost at least five patient lives.³⁰ One executive for the company noted that off-label marketing is the “status quo” and it “happens every day.”³¹ The company’s brochure even included a case study as a textbook example from a woman who, unbeknownst to the brochure-recipient surgeons, had died after the procedure.³² It took five years before federal prosecutors moved to indict the four company executives, who pled to lesser charges of misdemeanor “Responsible Corporate Officer Doctrine” violations expecting only fines or probation.³³ The grand jury instead indicted the company and its executives handing out fifty-two felony counts and forty-four misdemeanors.³⁴ The United States Attorney’s office called it “human experimentation.”³⁵

Ultimately, the company paid \$23 million in fines.³⁶ But the company was sold for \$20 billion later in 2012.³⁷ Twenty-three million dollars is only around 0.1% of \$20 billion; do company executives simply see this as the cost of doing business—i.e., part of their eminent domain? The four executives got prison sentences—with the judge sentencing some above the federal sentencing guidelines because he considered their crimes “egregious”—with the longest sentence being only nine months . . . even though five patients died.³⁸

limit. During the past decade, pharmaceutical behemoths . . . have paid billions in fines to settle charges that they engaged in off-label drug promotion. Yet cases continue to happen, in part because the potential profits often exceed the fines.”).

29. *Id.*

30. *Id.*

31. *Id.*

32. Kimes, *supra* note 17.

33. *Id.*

34. *Id.*

35. *Id.*

36. Kimes, *supra* note 17.

37. *Id.*

38. *Id.*

Recently, an off-label bone cement case involving another company settled for \$8.5 million.³⁹

Thus, orthopaedic medicine is vulnerable to manipulation by wealthy, ubiquitous device manufacturers that control the tools of the trade.⁴⁰

B. DETRIMENTAL “STRIKING SHIFTS” TO NEW IMPLANTS

Striking unexplainable shifts in implant use to devices that lead to worse patient outcomes may also signal industry control of orthopaedic medicine. The Research Committee (Committee) of the American Board of Orthopaedic Surgery (ABOS)—the certifying board for U.S. orthopaedic surgeons—published an article in 2008 noting a “striking shift” in hip fracture treatment, which lends credibility to Sarmiento’s assertion that the implant industry controls surgeon behavior because the new device was ultimately found to come at a higher cost with more complications.⁴¹

During the latter half of the twentieth century, the sliding compression hip screw and side plate (The “Plate”; Figure 1) became the “implant of choice” for the most common type of hip fracture in older patients—the intertrochanteric (IT) fracture of the hip.⁴² From 1999 to 2006, young surgeons rapidly switched to a new short intramedullary nail (The “Nail”; Figure 2) to

39. See Chad Terhune, *University of California OKs \$8.5 Million Payout in Spine Surgery Cases*, KAISER HEALTH NEWS (Aug. 1, 2016), <http://khn.org/news/university-of-california-oks-8-5-million-payout-in-spine-surgery-cases>.

40. Roy M. Poses, *Neurosurgeon Admits Kickbacks from Medical Device Manufacturers*, HEALTH CARE RENEWAL (Jan. 4, 2008), <http://hcrenewal.blogspot.com/2008/01/neurosurgeon-admits-kickbacks-from.html> (noting the “pervasiveness of conflicts of interest in health care” and suggesting that “more of these conflicts may cross the line to criminality than [] heretofore believed”).

41. Jeffrey O. Anglen & James N. Weinstein, *Nail or Plate Fixation of Intertrochanteric Hip Fractures: Changing Pattern of Practice: A Review of the American Board of Orthopaedic Surgery Database*, 90 J. BONE JOINT & SURGERY AM. 700, 705 (2008) (“Our data, which were collected from young orthopaedic surgeons in the beginning of their careers, confirm a higher rate of fracture and procedure-related complications and, at best, equivalent pain and deformity scores at the time of follow-up for patients managed with intramedullary nail fixation.”).

42. *Id.*

treat this type of hip fracture, in spite of higher costs and worse outcomes for the patients with the Nails.⁴³



Figure 1: The “Nail”⁴⁴



Figure 2: The “Plate”⁴⁵

Specifically, the Committee found that in 1999, young surgeons chose the Plate in 97% of IT hip fractures versus only 3% for the Nail.⁴⁶ But just seven years later in 2006, a “striking shift” had occurred such that the preference had flipped with new young surgeons choosing the Plate only 33% percent of the time, while choosing the Nail an incredible 67% percent of the time—representing a 2,133% increase in market share for the Nail in those seven years.⁴⁷ The rate of the shift was “striking” because young surgeons in 1999 only used the Nail 3% of the time, while use doubled to 6% the following year in 2000, more than doubled again the next year to 14% in 2001, almost doubled again to 27% over the next two years in 2003, and almost doubled again in the following two years to 53% by 2005, before reaching 67% in 2006 at the time the study was published.⁴⁸

43. *Id.* (“[I]mplant costs alone are estimated to be two to four times higher for intramedullary nail fixation.”).

44. Reproduced with permission from *OrthoInfo*. © American Academy of Orthopaedic Surgeons. <http://orthoinfo.aaos.org>. See *Hip Fractures*, AM. ACAD. OF ORTHOPAEDIC SURGEONS (last updated Apr. 2009), <http://orthoinfo.aaos.org/topic.cfm?topic=A00392>.

45. Reproduced with permission from *OrthoInfo*. © American Academy of Orthopaedic Surgeons. <http://orthoinfo.aaos.org>. See *Hip Fractures*, AM. ACAD. OF ORTHOPAEDIC SURGEONS (last updated Apr. 2009), <http://orthoinfo.aaos.org/topic.cfm?topic=A00392>.

46. Anglen & Weinstein, *supra* note 41, at 701.

47. *Id.*

48. *Id.* at tbl.2.

Why the shift? According to the Committee, the shift to the Nail does not appear to be based on scientific evidence of improved outcomes for patients.⁴⁹ The theoretical selling points of the Nail were the prospect of smaller incisions (“minimally invasive”), stronger fixation, shorter operating times, and less blood loss.⁵⁰ However, instead of benefits, the Committee found that “there were significant ($p < 0.05$) increases in the rates of bone fracture, unspecified surgical complications, and procedure-related complications for patients managed with [a Nail] as compared with those managed with a [Plate].”⁵¹ Citing multiple studies that included thousands of patients in total, the Committee noted “the *only consistent differences* found between the two fixation techniques seem to be an *increased rate of complications* (particularly intraoperative and postoperative fractures) and a *higher rate of reoperation* in association with [the Nail]” and noting that the “consensus from the orthopaedic literature is that [Nail] fixation is associated with a higher complication rate and no better outcomes.”⁵² The Committee acknowledged that “it is possible that some patients have had adverse effects because of this change in practice,”⁵³ which is likely an understatement. The Committee concluded by noting that the shift to the Nail resulted in “higher implant costs and surgeon fees, with no improvement in patient outcomes.”⁵⁴ Thus, the “striking shift” to the new device was clearly not based on scientific evidence or improved patient outcomes.

Was doctor greed a factor? Higher surgeon fees were noted by the Committee.⁵⁵ Therefore, financial incentives in the market place for the surgeon might play a role. For several reasons, surgeon enrichment seems like only a minor factor. First, the surgeons’ fees were only minimally higher—about \$235 per procedure⁵⁶ for a procedure that a typical surgeon in

49. *Id.* at 706 (noting “higher implant costs and surgeon fees, with no improvement in patient outcomes”).

50. *Id.* at 705.

51. *Id.* at 704–05.

52. Anglen & Weinstein, *supra* note 41, at 705 (emphasis added).

53. *Id.*

54. *Id.*

55. Anglen & Weinstein, *supra* note 41, at 706.

56. *Id.* (calculating that “the difference between the two procedures results in a pay differential of approximately \$235 in favor of intramedullary nail fixation”).

my experience might perform twenty-five to fifty times per year, thus totaling perhaps a \$5,875 to \$11,750 raise per year for surgeons already making over \$300,000 per year.⁵⁷ While not insignificant, it seems unlikely that two-thirds of young orthopaedic surgeons would abandon their moral compass to adopt a device with more complications jeopardizing patients' health for a 2% to 4% raise. It seems more likely that they are simply using the devices upon which they were trained—matching Sarmiento's observation that students simply use the educational system to "learn to use industry's tools."⁵⁸ In trying to explain the phenomenon, the Committee notes that, "[i]t may be that younger surgeons are responding to a change in training and that for some reason residents are currently being trained preferentially in [the Nail]."⁵⁹ Second, these are young orthopaedic surgeons who are more likely to continue the methods in which they were trained than abandon them for financial gain immediately upon entering the marketplace, starting a new practice, and trying to establish a name for themselves.⁶⁰ Third, the fact that payers are actually paying higher surgeon fees for worse outcomes with a more expensive device indicates forces other than young surgeons' negotiation skill must be at play, since young surgeons have little leverage in demanding higher fees as they start their careers.⁶¹ Other explanations seem more likely.

The implant companies had the biggest financial incentive to encourage the "striking shift" to the Nail. By converting orthopaedic surgeons to the Nail, the device maker could double to quadruple revenues because the price for the Nail was *two to four times higher* than that of the Plate.⁶² As Sarmiento observed, device manufacturers likely control the education process for orthopaedic surgeons who then simply do what they have been taught upon entering the market place; in many ways, orthopaedic surgery residency may be a sort of

57. Cf. MED. GROUP MGMT. ASS'N, PHYSICIAN COMPENSATION AND PRODUCTION SURVEY: 2008 REPORT BASED ON 2007 DATA 19 (2009) (reporting median compensation for orthopaedic surgeons as \$459,992 in 2008).

58. SARMIENTO, *supra* note 11, at 284.

59. Anglen & Weinstein, *supra* note 41, at 706.

60. See generally *id.*

61. Cf. *id.* at 706 (noting that certain external forces may encourage young surgeons to seek out "new techniques in a medical market that is constantly searching for the latest in technology").

62. *Id.* at 705.

microcosm of the Truman Show movie, in which young surgeons “accept the reality . . . presented” by their teachers under the directorship of the device manufacturers hidden behind the scenes.⁶³ In 2015, companies gave \$6.5 billion to doctors and teaching hospitals influencing research and patient care at academic medical centers.⁶⁴

Today, the Nail is still in use by many surgeons. Today’s Nail has been refined, so perhaps it is better; at this point, it is impossible to say. But I foresee a day coming when the Plate will be rolled back out as a “new” invention—at a higher price—and surgeons will undoubtedly strikingly shift back—hopefully this time with better outcomes for patients.

C. LACK OF REGULATORY CHANGE IN SPITE OF VOCIFEROUS CONCERNS

Another sign that Sarmiento may be correct about orthopaedic medicine being the marketing arm for the implant industry is the lack of any significant recent change in the FDA approval process for orthopaedic medical devices. The FDA clears implantable medical devices by two main pathways: (1) Premarket Approval (PMA) review requiring clinical trials, and (2) Premarket Notification (a.k.a., 510(k)) generally fast-tracking clearance by exempting devices from clinical studies confirming safety or efficacy if they can claim “substantial equivalence” to existing devices termed the “predicate” devices.⁶⁵ In 2012, 88% of orthopaedic devices were cleared by the shortcut 510(k) process versus only 53% for non-orthopaedic medical devices.⁶⁶ Orthopaedic devices cleared by the 510(k) “substantial equivalence” shortcut are “11.5 times more likely to be recalled” than devices cleared by the PMA

63. THE TRUMAN SHOW (Paramount Pictures 1998).

64. Terhune, *supra* note 39 (commenting on federal data).

65. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996) (noting that the 510(k) notification process is not comparable to the PMA process because the 510(k) review is “completed in an average of only twenty hours” whereas 1200 hours is necessary to complete a PMA review); see also Charles S. Day et al., *Analysis of FDA-Approved Orthopaedic Devices and Their Recalls*, 98A J. BONE & JOINT SURGERY AM. 517, 518 (2016); Kyle M. Fargen et al., *The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?*, 5 J. NEUROINTERVENTIONAL SURGERY 269 (2013).

66. Day et al., *supra* note 65, at 517.

process.⁶⁷ Thus, orthopaedic patients are a particularly vulnerable population.

In 2010, there was public outcry over several specific devices and the 510(k) process.⁶⁸ In 2011, the FDA asked the Institute of Medicine (IOM) to review the 510(k) clearance process and make recommendations to protect the health of the public while protecting the legitimate interests of the industry.⁶⁹ After extensive study, the IOM concluded that the 510(k) process was fatally “flawed”⁷⁰ because it generally does not evaluate safety and efficacy and cannot be transformed into such process.⁷¹ In its 298-page report, the IOM noted that the “substantial equivalence” clearance process “lacks the statutory basis to be a reliable premarket screen for safety and effectiveness” of moderate risk devices and recommended that Congress replace the system.⁷² The IOM recommended that the

67. *Id.*

68. See generally *Dangerous Medical Devices: Most Medical Devices Have Never Been Tested for Safety*, CONSUMER REPS., May 2012, at 24, <http://consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm>; Gardiner Harris, *F.D.A. Vows to Revoke Approval of Device*, N.Y. TIMES (Oct. 15, 2010), <http://www.nytimes.com/2010/10/15/health/policy/15fda.html> (noting that politics trumped science in the approval of a knee patch); Gardiner Harris, *U.S. Inaction Lets Look-Alike Tubes Kill Patients*, N.Y. TIMES (Aug. 21, 2010), <http://www.nytimes.com/2010/08/21/health/policy/21tubes.html> (noting resistance from the medical device industry and an approval process that discourages safety-related changes as factors in deaths related to some tubing connections); Barry Meier, *The Implants Loophole*, N.Y. TIMES (Dec. 17, 2010), <http://www.nytimes.com/2010/12/17/business/17hip.html> (recognizing potential problems with several devices that had been cleared through the 510(k) process, including an artificial hip); Alicia Mundy & Jared A. Favole, *FDA Rips Approval of Medical Device*, WALL ST. J. (Sept. 25, 2009), <http://www.wsj.com/articles/SB125382260933538517> (noting that Congressional pressure damaged the integrity of the FDA’s approval process).

69. INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA’S 510(K) CLEARANCE PROCESS AT 35 YEARS, xi (2011) [hereinafter IOM REPORT], <http://www.nap.edu/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance>.

70. INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA’S 510(K) CLEARANCE PROCESS AT 35 YEARS, 3 (2011) (report brief) [hereinafter REPORT BRIEF IOM], <http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf>.

71. IOM REPORT, *supra* note 69, at 5–6.

72. REPORT BRIEF IOM, *supra* note 70, at 3; IOM REPORT, *supra* note 69, at 198.

current system be replaced with an “integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle.”⁷³ Calls for change to the FDA’s approval process for implantable medical devices have been vociferous and have come from other highly respected authorities as well.⁷⁴

“Predicate creep”—the progression in which each generation of new devices evolves farther and farther from any device that has been proven safe and effective—makes the 510(k) process even more dangerous since the cumulative design changes may eventually lead to an implant with little resemblance to any device that has been found safe and effective.⁷⁵ Once the FDA clears a device via 510(k) or PMA, it can be used as a predicate for future devices without new safety or efficacy proof.⁷⁶ Thus, there may be a chain of devices (“predicate chain”) upon which a new device’s clearance rests, none of which have ever been proven safe or effective,⁷⁷ and the device’s foundation will be no stronger than the weakest link in its predicate chain.

The implant industry argues that more regulation will stifle innovation, yet the IOM found no evidence that the 510(k) process facilitates innovation.⁷⁸ Given Congress’ inaction amidst the cacophony of voices, changes to the FDA regulations

73. IOM REPORT, *supra* note 69, at 196.

74. IOM REPORT, *supra* note 69, at 15, 16 (noting there is concern that the 510(k) process is neither fostering innovation nor making safe/effective devices available to patients); *see also, e.g.*, Letter from Representatives Henry A. Waxman, Bart Stupak, & Frank Pallone, Jr., Comm. on Energy & Commerce, to Joshua M. Sharfstein, Principal Deputy Comm’r, FDA (May 11, 2009); Letter from Carmella Bocchino, Am.’s Health Ins. Plans, to Jeffrey Shuren, Div. of Dockets Mgmt., FDA (Mar. 19, 2010) (Document FDA-2010-N-0054-0047).

75. Arianne Freeman, *Predicate Creep: The Danger of Multiple Predicate Devices*, 23 ANNALS HEALTH L. ADVANCE DIRECTIVE 127, 127–29 (2014).

76. Sofia Bruera, *The 510(k) Fast Track and Medical Device Discovery*, TRIAL, Sept. 2013, at 35, 36; Fargen et al., *supra* note 65, at 272, 275 n.27.

77. Bruera, *supra* note 76.

78. IOM REPORT, *supra* note 69, at 4. *See generally* Daniel B. Kramer et al., *Regulation of Medical Devices in the United States and European Union*, 366 NEW ENG. J. MED. 848 (2012) (comparing U.S. and European regulatory environments for medical devices).

seem very unlikely.⁷⁹ The pharmaceutical and health manufacturing industry spent more than any other industry (\$240 million) on lobbying in 2015.⁸⁰ Instead of listening to the IOM, in March 2016, Congress proposed regulations to make it even easier to get orthopaedic devices to market.⁸¹

III. DIFFERENTIATING THE “CUTTING EDGE” OF SCIENCE FROM THE MARKETING EDGE OF BUSINESS: A LOOK AT SOME RECENT TOTAL JOINT REPLACEMENT DESIGN DEFECT CLAIMS

Joint replacement surgery has been around for over fifty years with little, if any, evidence that modern designs are actually an improvement on designs that were available over thirty years ago.⁸² By the 1970s and 80s, hip and knee replacement surgeries offered vast improvements in pain and function outcomes compared to their predecessor operations like fusion of the joint, resection of the joint, and osteotomy with joint realignment.⁸³ An early total hip design using the standard metal ball and a polyethylene socket from the 1970s—the Charnley hip—was later found to produce eighteen-

79. CONSUMER REPS., *supra* note 68, at 24 (identifying some of the critics).

80. *Top Organizations*, OPEN SECRETS, <https://www.opensecrets.org/lobby/top.php?showYear=2015&indexType=i> (last visited Oct. 5, 2016); *see also* Harris, *F.D.A. Vows to Revoke Approval of Device*, *supra* note 68 (noting politics trumped science in approval of knee patch); Harris, *U.S. Inaction Lets Look-Alike Tubes Kill Patients*, *supra* note 68 (noting resistance from the medical device industry and an approval process that discourages safety-related changes as factors in deaths related to some tubing connections); Mundy & Favole, *supra* note 68 (noting Congressional pressure damaged the integrity of the FDA’s approval process).

81. *See* Laura Laurenzetti, *Senate Passes Bill to Speed Medical Device Approvals*, FORTUNE.COM, (Mar. 10, 2016, 11:47 AM), <http://fortune.com/2016/03/10/senate-medical-device-bill/>.

82. *See, e.g.*, Vivek Mohan et al., *Monoblock All-Polyethylene Tibial Components Have a Lower Risk of Early Revision than Metal-Backed Modular Components*, 84 ACTA ORTHOPAEDICA 530 (2013) (reporting results of a “[r]egistry study of 27,657 primary total knee arthroplasties”). *See generally* IOM REPORT, *supra* note 69; SARMIENTO, *supra* note 11.

83. MERCER RANG, *THE STORY OF ORTHOPAEDICS* 35–54, 509–10 (2000) (tracing the history of hip arthroplasty, including the story of John Charnley, and the history of knee arthroplasty).

year success rates of 95%,⁸⁴ twenty-five-year success rates of 85%,⁸⁵ and thirty-five-year success rates of 78%.⁸⁶

Likewise, total knee replacements from the 1980s proved to be well designed. One of the early leaders in the field of total knee replacement, Zimmer, produced a total knee replacement that produced over 90% good-to-excellent outcomes, even in relatively young patients, (under age fifty-five at the time of their surgery) that were studied up to eighteen years after their surgery.⁸⁷

Joint replacement surgery brought expensive new medical devices to orthopaedic surgery, creating a lucrative industry that today accounts for over one-third of global orthopaedic revenues; almost three million total joints were performed worldwide in 2011 producing \$13.4 billion in revenues in a “highly competitive” market that is “95% controlled by [the] top eight players” with very little “share shift” over the decades.⁸⁸

Ignoring the ancient maxim, “the enemy of good is better,”⁸⁹ hundreds of modifications of existing successful designs were tried and various theoretical benefits marketed.⁹⁰ By the late 1990s, at least thirty-seven different total knee

84. See, e.g., Neumann et al., *supra* note 2, at 249 (noting a survival rate of 92 out of 103 hips).

85. Jaques Caton et al., *Over 25 Years’ Survival After Charnley’s Total Hip Arthroplasty*, 35 INT’L ORTHOPAEDICS 185, 185 (2011).

86. John J. Callaghan et al., *Survivorship of a Charnley Total Hip Arthroplasty. A Concise Follow-Up, at a Minimum of Thirty-Five Years, of Previous Reports*, 91 J. BONE & JOINT SURGERY AM. 2617, 2619 (2009).

87. See, e.g., JOHN INSALL ET AL., SURGERY OF THE KNEE 1658 (3d ed. 2001); Wayne A. Colizza, John N. Insall & Giles R. Scuderi, *The Posterior Stabilized Total Knee Prosthesis: Assessment of Polyethylene Damage and Osteolysis After a Ten-Year Minimum Follow-Up*, 77 J. BONE & JOINT SURGERY AM. 1713, 1718 (1995) (reporting 96% good or excellent results at eleven years follow-up); Diduch & Insall et al., *supra* note 2, at 576, 579; Steven H. Stern & John N. Insall, *Posterior Stabilized Prosthesis: Results After Follow-Up of Nine to Twelve Years*, 74A J. BONE & JOINT SURGERY AM. 980 (1992).

88. ORTHOKNOW, *supra* note 3, at 1, 2, 4.

89. See RATCLIFFE, *supra* note 5.

90. See 510(k) Premarket Notification, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> (showing 223 results when searching “total knee” in “Device Name”; showing 240 results when searching “total hip” in “Device Name”) (last updated Nov. 8, 2016); cf. R. Y. L. Liow & D. W. Murray, *Which Primary Total Knee Replacement: A Review of Currently Available TKR in the United Kingdom*, 79 ANN. ROYAL C. SURGERY ENG. 335 (1997) (analyzing TKR data from the United Kingdom).

replacement models were being marketed by fourteen different companies with one researcher noting that total knee models were changing so rapidly that published data was difficult to interpret “owing to the frequent modification of the prostheses.”⁹¹ Many of the design changes are minor or produce no obvious detrimental changes when studied years later.⁹² However, some seemingly innocuous design changes may convert a previously almost guaranteed (> 90% chance) good outcome to a bad outcome.⁹³

Dr. Sarmiento’s description of the development process for some “cutting edge” devices might explain cases where bad outcomes are foreseeable—where marketing overtakes science. Sarmiento described an offer from a “major medical device manufacturer” to market the “Sarmiento Hip Prosthesis.”⁹⁴ The company vice president flew to Sarmiento’s office and presented him with a “brand new, shining hip prosthesis” in a “velvet-lined box” and offered Sarmiento the opportunity to endorse it as his own, accept a \$250,000 check plus ongoing royalties, lend his name to the device, and hawk it as his own design.⁹⁵ The problem was that Sarmiento had never seen the device before that day; the company viewed Sarmiento’s input in the design process as unnecessary—in spite of his clinical experience and reputation as a world class hip surgeon.⁹⁶ Sarmiento admirably turned down the offer, but the company easily found a different professor within three months to become their salesman.⁹⁷

Later, when Sarmiento reminded an implant company president that Charnley’s total hip from the 1970s produced a higher rate of successful outcomes than any contemporary hip, the company president made it clear that he considered that information “totally irrelevant data.”⁹⁸ Instead, the implant

91. Liow & Murray, *supra* note 90, at 338, 340.

92. *Id.*

93. *Id.* at 339 (“It should be remembered that any modification can cause problems and do [*sic*] not automatically produce better results.”).

94. SARMIENTO, *supra* note 11, at 287.

95. *Id.*

96. *Id.*

97. *Id.* (“When I asked the distributor who had developed the prosthesis, he gave me the name of a senior professor at a respected medical school in the eastern United States.”).

98. *Id.* at 286.

company president was “concerned only with identifying those surgeons who were the most likely to be good salespeople for his products.”⁹⁹ The company president explained that “by the time his company released a new prosthesis to the public, they had already begun work on the next version.”¹⁰⁰ Scientific analysis and feedback from patients and surgeons, thus, did not appear to factor into the design process at all.

When the line between marketing and science is crossed by implant designers and manufacturers converting the “cutting edge” of science into the “marketing edge” of big business, the court system needs to step up and hold the risk-takers accountable to those who are injured. Judges appear to be struggling with these complex cases in ways that prejudicially favor big business to the detriment of patients.¹⁰¹ To help look at the issue, two recent alleged design defect issues—those raised in the metal-on-metal (MoM) hip cases and the Zimmer Flex™ knee cases—are explored in some detail followed by an analysis of the courts’ application of current design defect law in those cases and others. Nothing in this manuscript should be interpreted to allege that any device mentioned is defective in design; instead, the focus is intended to be on the judicial process—it is up to a jury to determine design defect, if given the chance.

A. TOTAL JOINT REPLACEMENT EXAMPLES IN THE LEGAL NEWS: THE METAL-ON-METAL TOTAL HIP AND THE ZIMMER FLEX TOTAL KNEE

The metal-on-metal (MoM) total hip and the Zimmer Flex (Flex) knee both prognosticated better outcomes than traditional hip and knee replacements, but unfortunately both have allegedly resulted in worse outcomes with numerous lawsuits filed.¹⁰² The MoM hip touted the elimination of

99. *Id.* at 286.

100. *Id.* at 285–86.

101. See Allan Kanner & M. Ryan Casey, *Daubert and the Disappearing Jury Trial*, 69 U. PITT. L. REV. 281, 317–18 (2007).

102. See, e.g., *Kransky v. DePuy Orthopaedics Inc.*, No. BC456086 (L.A. Cty. Super. Ct. Cal., Mar. 8, 2013); *Smith v. DePuy Orthopaedics Inc., et al.*, No. CJ201105804 (Tulsa Cty. D. Ct. Okla., Feb. 4, 2015); Annotation, *\$2.5 Million Verdict in Suit Alleging Defective Hip Transplant*, 35 VERDICTS, SETTLEMENTS & TACTICS Art. 50 (2015). See generally CHARLES J. NAGY, JR., HIP PROSTHESES, AM. L. PRODS. LIAB. 3D § 91:65 (citing William Jordan,

polyethylene debris—a potential source for late failure of the traditional metal-on-polyethylene design (“traditional total hips”)—and lower dislocation rates as potential benefits,¹⁰³ and the Flex knees promoted more knee flexion including a knee specially designed for women—who account for two-thirds of U.S. total knee patients.¹⁰⁴

1. Metal-on-Metal Total Hips

Metal-on-metal total hips presented the potential “better” outcome of no polyethylene debris (a mode of failure for traditional metal-on-polyethylene hips) and decreased likelihood of hip dislocations compared to the “good” traditional total hips—like the Charnley hip mentioned above.¹⁰⁵ After early versions of MoM hips had high revision rates in the 1970-80s,¹⁰⁶ MoM hips reemerged in the late 1990s with over one million MoM hips performed worldwide since 1996.¹⁰⁷ One MoM hip that has received a lot of legal attention recently—the ASR™ XL™ Acetabular System (DePuy, Johnson &

Annotation, *Products Liability: Medical Devices*, 33 VERDICTS, SETTLEMENTS & TACTICS Art. 53 (2013)).

103. See S.J. MacDonald et al., *Metal-on-Metal Versus Polyethylene in Hip Arthroplasty: A Randomized Clinical Trial*, 406 CLINICAL ORTHOPAEDICS & RELATED RES. 282 (2003) (testing the accuracy of claims of reduced polyethylene debris and decreased likelihood of dislocation).

104. CAROL J. DEFANCES ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., 2003 NATIONAL HOSPITAL DISCHARGE SURVEY ADVANCE DATA NO. 359, 16, tbl.10 (July 8, 2005).

105. See MacDonald et al., *supra* note 103 (discussing decreased debris); Thomas M. Smith et al., *Metal-on-Metal Total Hip Arthroplasty with Large Heads may Prevent Early Dislocation*, 441 CLINICAL ORTHOPAEDICS & RELATED RES. 137, 139–40 (2005) (discussing decreased dislocation).

106. Brent M. Ardaugh et al., *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW ENG. J. MED. 97, 98 (2013); *see also* Bruera, *supra* note 76, at 36.

107. See Michael Bolognesi & Cameron Ledford, *Metal-on-Metal Total Hip Arthroplasty: Patient Evaluation and Treatment*, 23 J. AM. ACAD. ORTHOPAEDIC SURGERY 724, 724–25 (2015); Kevin J. Bozic et al., *The Epidemiology of Bearing Surface Usage in Total Hip Arthroplasty in the United States*, 91 J. BONE & JOINT SURGERY AM. 1614 (2009) (reporting a data set, collected during fifteen months in 2005-06, of more than 100,000 hip arthroscopy patients); *see also* AM. ACAD. OF ORTHOPAEDIC SURGEONS (AAOS), INFORMATION STATEMENT: CURRENT CONCERNS WITH METAL-ON-METAL HIP ARTHROPLASTY 1 (2012), http://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1035%20Current%20Concerns%20with%20Metal-on-Metal%20Hip%20Arthroplasty.pdf [hereinafter AAOS INFORMATION STATEMENT].

Johnson®)—was introduced in the U.S. market in December 2005 after being cleared through the 510(k) “substantial equivalence” pathway, and over 100,000 units were implanted before its voluntary recall in August 2010.¹⁰⁸

Concern first emerged over MoM hips in 2008 when international databases (termed “joint registries”) in Britain and Australia reported revision rates two- to three-fold higher among MoM hips than traditional total hips.¹⁰⁹ The FDA responded by noting that overseas databases may not necessarily correlate with experiences in the United States.¹¹⁰ By 2009, around 300 complaints mostly involving early revision surgery had already been filed with the FDA.¹¹¹ Adverse reaction to metal debris was found to be the cause of failure in several studies.¹¹² In addition, elevated levels of cobalt and chromium (among the metal components of MoM devices) were found in the MoM patients’ bloodstreams with associated chromosomal aberrations,¹¹³ along with neurologic and cardiac abnormalities.¹¹⁴ Finally, in 2011, the FDA announced concerns

108. Fargen et al., *supra* note 65; Barry Meier, *With Warning, a Hip Device is Withdrawn*, N.Y. TIMES (Mar. 9, 2010), <http://www.nytimes.com/2010/03/10/business/10device.html>; *see also* U.S. ASR Hip Settlement Program Website, <https://www.usasrhipsettlement.com> (last visited Sept. 7, 2016).

109. *See* AUSTL. ORTHOPAEDIC ASS’N NAT’L JOINT REPLACEMENT REGISTRY, ANNUAL REPORT 2008 (2008); Bolognesi & Ledford, *supra* note 107, at 724, 730 (citing NAT’L JOINT REGISTRY FOR ENG. AND WALES, SEVENTH ANNUAL REPORT (2008), <http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/5th%20Annual.pdf>; *see also* AAOS INFORMATION STATEMENT, *supra* note 107, at 1.

110. *Recalls*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241770.htm#3> (last visited Sept. 7, 2016) [archival: http://www.burgsimpson.com/wp-content/uploads/sites/9/2015/07/FDA_Metal-on-Metal-Hip-Implants.pdf].

111. Fargen et al., *supra* note 65, at 269 (quoting Meier, *supra* note 108).

112. *See* Bolognesi & Ledford, *supra* note 107, at 724; D.J. Langton et al., *Early Failure of Metal-on-Metal Bearings in Hip Resurfacing and Large-Diameter Total Hip Replacement: A Consequence of Excess Wear*, 92 J. BONE & JOINT SURGERY BRIT. 38, 38 (2010); H. Pandit et al., *Pseudotumours Associated with Metal-on-Metal Hip Resurfacings*, 90 J. BONE & JOINT SURGERY BRIT. 847, 847 (2008).

113. *See* E. Dunstan et al., *Chromosomal Aberrations in the Peripheral Blood of Patients with Metal-on-Metal Hip Bearings*, 90 J. BONE & JOINT SURGERY AM. 517, 521–22 (2008).

114. *See* Stephen S. Tower, *Arthroprosthetic Cobaltism: Neurological and Cardiac Manifestations in Two Patients with Metal-on-Metal Arthroplasty: A Case Report*, 92 J. BONE & JOINT SURGERY AM. 2847, 2850 (2010).

about MoM hips and ordered five manufacturers to perform postmarket surveillance of their implants.¹¹⁵ Three implant companies voluntarily recalled some of their MoM hip devices.¹¹⁶

The news kept getting worse for MoM hips when, in March 2013, British researchers reported that the failure rate of “metal-on-metal” total hips was much greater than other designs; the researchers stated that the devices had “poor implant survival compared to other options and *should not be implanted*.”¹¹⁷ Specifically, a British study of 400,000 total hip implant patients found a 6.2% failure rate for MoM hips compared to only 1.7% for traditional total hip devices.¹¹⁸

In March 2013, a California jury awarded over \$8 million to a plaintiff in an ASR MoM hip case.¹¹⁹ In November 2013, DePuy settled an estimated 7200 lawsuits involving the ASR hips for \$2.5 billion, with over 94% of the plaintiffs accepting the settlement while some remain active in the courts.¹²⁰ In February 2015, an Oklahoma jury awarded a plaintiff with bilateral ASR hips \$2.5 million after both implants allegedly failed.¹²¹

115. See *Effectiveness of Metal-on-Metal Hip Implants*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm331960.htm> (last updated Mar. 14, 2016); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-815, FDA ORDERED POSTMARKET STUDIES TO BETTER UNDERSTAND SAFETY ISSUES, AND MANY STUDIES ARE ONGOING, <http://www.gao.gov/assets/680/672860.pdf> (2015).

116. Bolognesi & Ledford, *supra* note 107, at 725.

117. See Alison J. Smith et al., *Failure Rates of Stemmed Metal-on-Metal Hip Replacements: Analysis of Data from the National Joint Registry of England and Wales*, 379 THE LANCET 1199, 1199 (2012), [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)60353-5/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60353-5/abstract) (emphasis added).

118. *Id.* at 1201–02 (reporting failure rate metal-on-metal hips); Metal-on-Metal Hip Joints ‘Should Not Be Implanted,’ British Study Says, 19 WESTLAW J. MED. DEVICES 1 (2012) (reporting failure rate for traditional total hip devices).

119. NAGY, *supra* note 102 (analyzing *Kransky v. DePuy Orthopaedics Inc.*, No BC456086 (L.A. Cty. Super. Ct. Cal., Mar. 8, 2013)).

120. *E.g.*, *Kransky v. DePuy Orthopaedics Inc.*, 29 NAT'L JURY VERDICT REV. & ANALYSIS Art. 12 (2014); accord *Johnson & Johnson's DePuy Wins First Trial over Pinnacle Hips: Herlihy-Paoli v. DePuy Orthopaedics*, 21 WESTLAW J. MED. DEVICES 2 (2014).

121. See NAGY, *supra* note 102.

Since settling the ASR lawsuits, DePuy (now part of Johnson & Johnson) has taken a different approach with one of its other MoM hips—the Pinnacle™ hip. There has been no recall of the Pinnacle MoM hips, but the company reportedly “stopped selling the MoM Pinnacle device in 2013.”¹²² Over 6600 lawsuits are pending involving the MoM Pinnacle hips.¹²³ DePuy spokeswoman Mindy Tinsley said the company is committed to a “long-term and vigorous defense” of the litigation claiming the MoM device “was appropriately developed, thoroughly tested and responsibly marketed.”¹²⁴ In the first bellwether trial over Pinnacle, a Texas jury found DePuy not liable after the company blamed the surgeon for “improperly positioned” implants in a case where the plaintiff’s blood cobalt level rose to eighty-five times the normal level.¹²⁵ DePuy sought to eliminate at least six experts proffered by the plaintiffs’ steering committee; the ultimate outcome of the *Daubert* rulings on those experts in motions in limine are pending and will be considered closer to trial.¹²⁶

On March 17, 2016, DePuy’s strategy may have backfired when a Texas jury awarded five Texans a total of \$502 million for injuries related to the Pinnacle MoM hips.¹²⁷ The jury found that the devices were *defective*, and that DePuy was guilty of gross negligence and fraud.¹²⁸ DePuy promised to appeal with Ms. Tinsley again asserting the MoM devices are “backed by a strong record of safety and effectiveness.”¹²⁹ Some MoM hip devices appear to remain available on the company’s website.¹³⁰

122. 21 WESTLAW J. MED. DEVICES, *supra* note 120, at *1.

123. *Id.* at *1.

124. *Id.* at *1 (internal quotations omitted).

125. *Id.* at *1.

126. *See In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *14 (N.D. Tex. Jul. 18, 2014).

127. *See* Lisa Schencker, *Johnson and Johnson Must Pay \$502 Million over Hip Devices*, MOD. HEALTHCARE (Mar. 17, 2016), <http://www.modernhealthcare.com/article/20160317/NEWS/160319898/johnson-johnson-must-pay-502-million-over-hip-devices>.

128. *Id.*

129. *Id.* (internal quotations omitted).

130. *See* DEPUY SYNTHES, *Hip Reconstruction: Products*, <http://www.depuysynthes.com/hcp/hip/products/qs/PINNACLE-Bantam-Acetabular-Cup> (last visited Sept. 5, 2016).

In February 2016, the FDA issued a final order saying that with regard to two specific types of MoM hips, “there is insufficient evidence and information to conclude that general controls in combination with special controls would provide reasonable assurance of the safety and effectiveness of these devices.”¹³¹ The FDA then classified the devices as “higher risk” (Class III) and demanded that PMA applications be filed with the FDA by May 18, 2016 if the “manufacturer wants to continue marketing their MoM total hip replacement devices and/or market new MoM total hip replacement devices.”¹³² The theoretical advantages of MoM hips hawked by device manufacturers now appear questionable at best, with a recent study suggesting that the results of MoM hips appear to be inferior to traditional total hips.¹³³

2. Zimmer Flex Total Knees

The Zimmer NexGen® Flex total knees (Flex)—including the “Gender Solutions™ High-Flex Knee” and other versions—tout the potential for “better” knee flexion to replace the “good” flexion of prior models.¹³⁴ Two-thirds of all total knees in the United States are performed on women,¹³⁵ and the Gender Solutions Flex knee is marketed especially for females as “the first and only knee replacement shaped to fit a woman’s anatomy.”¹³⁶ The marketing information says, “[f]rom the cells in their bodies to their taste in clothes, it’s no surprise that women are different from men [R]esearch shows women and men are different all the way down to their knees[,]” and

131. See U.S. FOOD & DRUG ADMIN., *FDA Activities*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241769.htm> (last visited Mar. 23, 2016).

132. *Id.*

133. William M. Mihalko et al., *How Have Alternative Bearings and Modularity Affected Revision Rates in Total Hip Arthroplasty*, 472 CLINICAL ORTHOPAEDICS & RELATED RES. 3747, 3755 (2014) (“The systematic review concerning alternative bearings revealed that small head MoM had similar but large head MoM had inferior results compared with both standard and highly crosslinked polyethylene mated with any hard material.”).

134. The Flex knee is included here because allegations of design defect are being raised in many lawsuits, mentioned *infra*, such that the device serves as a current example of the medical device trial process under *Daubert*.

135. DEFRANCES ET AL., *supra* note 104.

136. See, e.g., *Marketing Material for the Zimmer Gender Solutions High-Flex Knee*, BOTSFORD, http://www.botsford.org/medical_services/orthopedics/pdf/ZimmerGenderSolutionsHighFlexKnee.pdf (last visited Sept. 5, 2016).

claims that thickness in the front of traditional knee replacements may make women's knees feel "bulky."¹³⁷ The company's brochure shows a woman curled up on the couch with knees comfortably flexed and says simply, "Because Women and Men are Different."¹³⁸

Interestingly, the inventor of the Flex knees, Dr. John Insall,¹³⁹ did not invent the Flex knee for women—nor really for Americans at all. While flying home from Japan on April 28, 1995, Dr. Insall proposed changes to his earlier NexGen total knee design to allow more knee flexion to accommodate the "cultur[al] needs of Japanese knee replacement patients."¹⁴⁰ Dr. Insall said, "we are involved in developing a more natural 'high flexion' knee prosthesis to accommodate" higher flexion demands of Middle Eastern and Asian patients who "need significant knee flexion during prayer."¹⁴¹ If the inventor envisioned the mass marketing of this device to Americans or to American women, this author cannot find such reference at this time.¹⁴²

137. Zimmer, *Knee Replacement Surgery for Women: Key Differences Between Women's and Men's Knees*, <http://www.zimmer.com/patients-caregivers/article/knee/knee-surgery-women.html> (last visited Sept. 5, 2016).

138. Zimmer, *Brochure for Zimmer Gender Solutions NexGen High Flex Implants*, <http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/medical-professionals/knee/zimmer-gender-solutions-NexGen-high-flex-implants-brochure.pdf> (last visited Sept. 5, 2016).

139. Disclosure: The author implanted Zimmer NexGen Legacy™ PS total knees throughout his career as an orthopaedic surgeon. The author completed a fellowship in knee reconstruction and sports medicine under the tutelage of Dr. Insall and his colleagues at the Insall-Scott-Kelly (ISK) Institute in New York City in 1996–97 and has co-authored several papers with Dr. Insall. *See, e.g.*, Frankie M. Griffin, John N. Insall & Giles R. Scuderi, *Accuracy of Soft Tissue Balancing in Total Knee Arthroplasty*, 15 J. ARTHROPLASTY 970 (2000); Frankie M. Griffin, John N. Insall & Giles R. Scuderi, *The Posterior Condylar Angle in Osteoarthritic Knees*, 13 J. ARTHROPLASTY 812 (1998); Frankie M. Griffin et al., *Total Knee Arthroplasty in Patients Who Were Obese with 10 Years Followup*, 356 CLINICAL ORTHOPAEDICS. & RELATED RES. 28 (1998); Frankie M. Griffin et al., *Anatomy of the Epicondyles of the Distal Femur*, 15 J. ARTHROPLASTY 354 (2000). *See generally* Giles R. Scuderi, W. Norman Scott & Gregory H. Tchejeyan, *The Insall Legacy in Total Knee Arthroplasty*, 392 CLINICAL ORTHOPAEDICS & RELATED RES. 3, 3–14 (2001) (profiling Dr. Insall).

140. *Scott v. Zimmer, Inc.*, 889 F. Supp. 2d 657, 663 (D. Del. 2012); *see also* Scuderi, Scott & Tchejeyan, *supra* note 139.

141. INSALL ET AL., *supra* note 87, at 1555.

142. During his one year of training with Dr. Insall in 1996–97, the author also cannot recall Dr. Insall ever mentioning in a clinical setting any concern

Asians are of smaller build than Americans and may thus put less stress upon a knee in deep flexion than taller¹⁴³ and heavier¹⁴⁴ Americans. Also, anatomic differences in the contact areas of kneecaps of Westerners versus those in Eastern cultures have been reported, which may have implications for deep knee flexion.¹⁴⁵ So it would not be surprising if Dr. Insall never intended the Flex knee for Americans at all.

So was there really a need for Americans, and particularly American women, to have the 155° of flexion promised by the Flex knee and the associated design changes? The Flex knee's predecessor—the non-Flex Zimmer NexGen knee—was doing well and demonstrated the “lowest rate [of revision] for a widely used total-knee device” in one study.¹⁴⁶ In traditional Western medical books, normal knee flexion appears to be considered up to 130°.¹⁴⁷ The drawing in Figure 3 demonstrates how knee flexion (bending) is measured:

that American women needed more knee flexion than provided by traditional total knee designs.

143. The average height of 50 to 79 year old Japanese men/women is 168.6/155.9 cm compared to the average height of 50 to 79 year old American men/women of 174.9/161.0 cm. See MINISTRY OF EDUC., CULTURE, SPORTS, SCI. & TECH., RESULTS OF AGE PHYSIQUE MEASUREMENT, http://www.mext.go.jp/b_menu/toukei/001/022/2004/002.pdf (Japanese government statistics); CHERYL D. FRYAR ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., ANTHROPOMETRIC REFERENCE DATA FOR CHILDREN AND ADULTS: UNITED STATES, 2007–2010, at 13 tbl.9, 15 tbl.11 (2010), http://www.cdc.gov/nchs/data/series/sr_11/sr11_252.pdf.

144. The average North American weight is 177.9 pounds compared to the average Asian weight of 127.2 pounds. See FRYAR ET AL., *supra* note 143 at 8 tbl.4, 10 tbl.6; Sarah C. Walpole et al., *The Weight of Nations: An Estimation of Adult Human Biomass*, 12 BMC PUB. HEALTH 439, tbl.3 (2012) (comparing worldwide obesity statistics, by geographical region).

145. INSALL ET AL., *supra* note 87, at 16 (“Because the odd facet only makes contact with the femur in extreme flexion (such as in the act of squatting), this facet is habitually a noncontact zone in humans in Western cultures, a fact that is thought to have some pathological significance.”); cf. Clarke et al., *Anatomy*, MUSCULOSKELETAL KEY fig.1-6, <http://musculoskeletalkey.com/anatomy-3/> (last visited Nov. 8, 2016) (“Because the odd facet makes contact with the femur only in extreme flexion (such as in the act of squatting), this facet is habitually a noncontact zone in human in Western cultures, a fact that is thought to have some pathological significance.”).

146. Joe Carlson, *Device Maker Faces Massive Liability Case over Knee Replacement Systems*, MOD. HEALTHCARE (May 4, 2013), <http://www.modernhealthcare.com/article/20130504/MAGAZINE/305049979>.

147. E.g., BARBARA BATES, A GUIDE TO PHYSICAL EXAMINATION AND HISTORY TAKING 469 (5th ed. 1991).

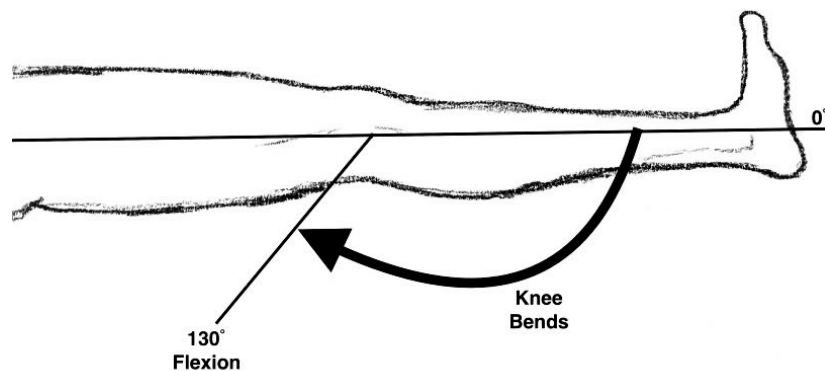


Figure 3

A suitable goal for flexion after rehabilitation of a total knee patient is around 110° , which allows patients to rise and sit in a chair and to traverse stairs.¹⁴⁸ An aggressive goal could be 135° , which some patients might use in bathing.¹⁴⁹ The Knee Society—a highly-respected group of the top knee surgeons in the world—rates a knee with 125° of flexion as a perfect score on its rating scale, which was a revision of an older scale (HSS score) that required 144° for a perfect score.¹⁵⁰

This author cannot find convincing scientific justification for pursuing 155° of knee flexion in the fifty- to eighty-year-old¹⁵¹ American patients who undergo the vast majority of total knee replacements in the United States. The Zimmer brochure for its Gender Solutions knees focuses more on the change of the shape of the implant as a selling point to better fit the female bony anatomy, but also notes that the Gender Solutions knee “safely accommodates high flexion—up to 155 degrees—for patients with the ability and desire to do so.”¹⁵² But, the

148. P.J. Rowe et al., *Knee Joint Kinematics in Gait and Other Functional Activities Measured Using Flexible Electrogoniometry: How Much Knee Motion is Sufficient for Normal Daily Life?*, 12 *GAIT & POSTURE* 143, 143–47, 155 (2000).

149. *Id.*

150. INSALL ET AL., *supra* note 87, at 1508–11 (quoting John N. Insall et al., *Rationale of The Knee Society Clinical Rating System*, 248 *CLINICAL ORTHOPAEDICS & RELATED RES.* 13 (1989)).

151. AAOS, *Orthoinfo: Total Knee Replacement*, <http://orthoinfo.aaos.org/topic.cfm?topic=a00389> (last visited Sept. 7, 2016).

152. Zimmer, *supra* note 138.

inventor's design modifications were reportedly primarily meant to achieve higher flexion.¹⁵³

Unfortunately, some have alleged that Zimmer Flex knees have under-performed their non-Flex counterparts to the detriment of patients. In early 2006, Dr. Richard Berger—one of Zimmer's highly-paid, “master” surgeons—notified the company that too many of his Flex knee patients were experiencing an unusual amount of pain and radiographic loosening.¹⁵⁴ Zimmer told Berger that he was the only surgeon having that problem and blamed it on his surgical technique.¹⁵⁵ In 2007, Berger stopped using the Flex knees, even though he was still a paid Zimmer consultant.¹⁵⁶ In that same year, authors unaffiliated with Berger reported “a marked rate of early loosening” with a 21% revision rate within two years for their NexGen Flex knees (and 38% revision rate at thirty-two months).¹⁵⁷

In 2009, Zimmer did not renew Dr. Berger's contract after previously paying him over \$8 million during the prior ten years.¹⁵⁸ In 2010, Berger presented the results of 108 Flex knee patients to a national meeting of the American Academy of Orthopaedic Surgeons (AAOS) reporting an 8.3% revision rate and a 36% radiographic short-term loosening rate.¹⁵⁹ Berger called the revision rate of that version of the Flex knee “horrific” and recommended that Zimmer pull it off of the market.¹⁶⁰

153. Scuderi, Scott & Tchejeyan, *supra* note 139, at 6 fig.8 (“Intrigued by the desire to bring total knee arthroplasty to regions of the world, such as Asia and the Middle East, where patients require higher degrees of flexion for their social and religious activities, Insall designed the LPS-Flex Knee Prosthesis”); INSALL ET AL., *supra* 87, at 1555.

154. See Barry Meier, *Surgeon vs. Knee Maker: Who's Rejecting Whom?*, N.Y. TIMES (Jun. 19, 2010), <http://www.nytimes.com/2010/06/20/business/20knee.html>.

155. *Id.*

156. *Id.*

157. H.S. Han et al., *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilised-Flex Total Knee Replacement*, 89B J. BONE & JOINT SURGERY BRIT. 1457, 1457 (2007).

158. Meier, *supra* note 154.

159. *Id.*; Zimmer, Statement on the Zimmer NexGen CR-Flex Porous Femoral Component (Form 8-K) EX-99.1 (Mar. 12, 2010), <https://www.sec.gov/Archives/edgar/data/1136869/000095012310023796/c56948exv99w1.htm>.

160. *Surgeons Challenge Zimmer to Pull High Flex NexGen Knees Off Market Because of High Loosening Rates*, ORTHOSTREAMS, <http://>

Zimmer blamed the problem on Berger's surgical technique, as Berger noted: "Suddenly, I went from someone who was their master teacher to someone who didn't know what he was doing."¹⁶¹ After Berger's 2010 presentation to the AAOS, Zimmer defended the device in its March 2010 Securities and Exchange Commission (SEC) filing citing successful results in the Australian joint registry.¹⁶²

Over 1500 lawsuits have been filed against Zimmer over its NexGen Flex knees.¹⁶³ In November 2015, Zimmer won the first MDL bellwether trial.¹⁶⁴ The presiding trial judge faced complex *Daubert* challenges regarding the reliability of testimony by multiple, highly qualified, scientific experts; she excluded some expert testimony while allowing others—sometimes paradoxically.¹⁶⁵ The trial judge's educational background included a history and humanities undergraduate major, law school, and a prestigious judicial clerkship.¹⁶⁶ Her work background includes employment discrimination law, commercial litigation, administrative law judicial duties, and work as a United States Magistrate Judge.¹⁶⁷ In spite of the absence of any significant scientific background, the judge wrote nearly two hundred pages analyzing complex motions for exclusion of expert testimony regarding detailed intricacies of total knee arthroplasty.¹⁶⁸

The judge excluded the following Plaintiff's experts' testimony: (1) defective design testimony and causation

orthostreams.com/2010/03/surgeons-challenge-zimmer-to-pull-high-flex-nexgen-knees-off-market-because-of-high-loosen-rates/ (last visited Sept. 7, 2016).

161. Meier, *supra* note 154.

162. *Id.*; Zimmer, *supra* note 159.

163. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5145546, at *1 (N.D. Ill. Aug. 31, 2015); Jessica Dye, *Zimmer Wins First U.S. Trial Over NexGen Flex Knee Devices*, REUTERS (Nov. 6, 2015, 5:30 PM), <http://www.reuters.com/article/zimmer-biomet-NexGen-idUSL1N1312VM20151106>.

164. Dye, *supra* note 163.

165. For an example of several of the trial judge's *Daubert* rulings, see *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5145546, at *1 (N.D. Ill. Aug. 31, 2015).

166. *Biographical Directory of Federal Judges: Pallmeyer, Rebecca R.*, FED. JUD. CTR., <http://www.fjc.gov/servlet/nGetInfo?jid=2802> (last visited Oct. 12, 2016).

167. *Id.*

168. See, e.g., *infra* notes 169–79.

testimony from an NYU professor of orthopaedics with expertise in biomechanics, who performed over 100 total knee replacements per year, gave over 200 lectures, and wrote textbooks (Dr. Fetto),¹⁶⁹ (2) defective design and causation testimony from the plaintiff's treating doctor (Dr. Klein),¹⁷⁰ and (3) defective design testimony and 510(k) testimony from a doctor of physiology and engineering who had previously worked at the FDA (Dr. Samaras).¹⁷¹

The judge allowed for the plaintiff: (1) design defect testimony from a retired professor (Dr. Brown),¹⁷² and (2) testimony only regarding the plaintiff's treatment from her surgeon (Dr. Klein).¹⁷³

The judge excluded the following Defense experts' testimony: (1) x-ray alignment testimony regarding the plaintiff's implant from a Stanford orthopaedic surgeon (Dr. Goodman),¹⁷⁴ (2) retrieval analysis testimony from failed Flex knees by a Hospital for Special Surgery (HSS) research scientist, Dr. Timothy Wright,¹⁷⁵ and (3) 510(k) testimony from an FDA expert (Ulatowski).¹⁷⁶

On the Defense side, the judge allowed: (1) computer model testimony on Finite Elemental Analysis of the forces on the flexed knee by a research scientist from Scripps (Dr. D'Lima),¹⁷⁷ (2) epidemiology testimony from a pediatric spine

169. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 3669933, at *19 (N.D. Ill. June 12, 2015).

170. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 3799534, at *4–5 (N.D. Ill. June 17, 2015) (partially ignoring Dr. Klein's testimony on FED. R. CIV. P. 26 grounds).

171. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5145546, at *2–3 (N.D. Ill. Aug. 31, 2015).

172. *In re Zimmer*, 2015 WL 3669933, at *8.

173. *In re Zimmer*, 2015 WL 3799534, at *4–5 (allowing this portion of the testimony as not subject to the Rule 26 requirements mentioned in note 170, *supra*).

174. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5095727, at *6–8 (N.D. Ill. Aug. 27, 2015).

175. *Id.* at *3–5.

176. *In re Zimmer*, 2015 WL 5145546, at *11.

177. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 4880953, at *1 (N.D. Ill. Aug. 13, 2015); Ronald V. Baker, *Witness Can Show Computer Model of Knee Implant in Zimmer NexGen MDL Bellwether Trial*, 22 WESTLAW J. MED. DEVICES 6, at *1 (Sept. 9, 2015); Darryl D'Lima, *In Vivo Knee Forces During Recreation and Exercise After Knee Arthroplasty*, 466 CLINICAL ORTHOPAEDICS & RELATED RES. 2605, 2605–11

surgeon regarding his findings for the Zimmer total knee using the Australian registry database and his review of the literature (Dr. Vitale),¹⁷⁸ (3) epidemiological testimony on his review of the clinical literature by Dr. Timothy Wright at HSS.¹⁷⁹

At least one author attributed Zimmer's success in the trial to "[e]xpert [t]akedown" with Zimmer "successfully curbing its adversary's expert testimony" under *Daubert*.¹⁸⁰ One of the attorneys noted, "the loss of expert testimony . . . was clearly very detrimental to the plaintiffs."¹⁸¹

Zimmer blamed the plaintiff's failed total knee on her operating surgeon, claiming he "hadn't properly secured the implants in place."¹⁸² Three more bellwether cases will be selected from pools of cases selected by Zimmer and the plaintiffs.¹⁸³ "The next bellwether trial will be a case selected by Zimmer."¹⁸⁴

B. EXPERT TESTIMONY WILL DETERMINE THE OUTCOME OF MOST COMPLEX ORTHOPAEDIC DESIGN DEFECT CASES AND *DAUBERT* STANDS AS A POTENTIAL ARTIFICIAL AND UNREASONABLE BARRIER UNLESS INTERPRETED FAIRLY

Design defect law is complex and varies depending upon the jurisdiction; but regardless of the prevailing law, expert testimony is likely to determine the outcome at almost any orthopaedic device trial.¹⁸⁵ The Supreme Court in *Daubert* provided a framework for judicial analysis of the admissibility of expert testimony under Federal Rules of Evidence Rule 702 which has the potential to become an artificial and

(2008) (discussing the level of force involved in various activities for post-operative patients).

178. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5050214, at *4, *13 (N.D. Ill. Aug. 25, 2015).

179. *In re Zimmer*, 2015 WL 5095727, *supra* note 174, at *8.

180. Sindhu Sundar, *Zimmer's Expert Takedown Poses Hurdles for Knee Patients*, LAW360 (Nov. 12, 2015, 5:43 PM) <http://www.law360.com/articles/724921/zimmer-s-expert-takedown-poses-hurdles-for-knee-patients>.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. See John Hein, *When Reliable is Reliable Enough: The Use of Expert Testimony After Kumho Tire v. Carmichael*, 6 WASH. U. J. L. & POL'Y 223, 223 (2001).

unreasonable barrier to recovery, for plaintiffs in orthopaedic design defect cases, if interpreted prejudicially in favor of the device industry.¹⁸⁶

1. Expert Testimony Will Likely Be Determinative in Virtually All Cases of Alleged Design Defect for Orthopaedic Implants

Proper handling of expert testimony is the key to obtaining just outcomes in orthopaedic implant design cases. Less complex general design defect problems have been described as ill-suited for litigation due to (1) the complexity of the issues, (2) the polycentricity of the analysis required, and (3) the dearth of qualified judges and juries capable of dealing with the expert testimony involved.¹⁸⁷

There is no universal definition for “design defect,” and different jurisdictions (and sometimes judges within the same jurisdiction) interpret the same tests in different ways.¹⁸⁸ Definitions of “defect” include: “fail[s] to perform in a manner reasonably . . . expected in light of [its] nature and intended function” or is “unreasonably dangerous,”¹⁸⁹ fails to “meet reasonable expectations of the ordinary consumer as to its safety,”¹⁹⁰ would be withheld from the market due to known risks by a “reasonable and humane seller,”¹⁹¹ fails to “fulfill a policy assumption,”¹⁹² “fails to meet reasonable consumer expectations,”¹⁹³ among other definitions.¹⁹⁴ The Restatements say that one engaged in the business of selling or distributing a

186. See *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 (1993) (“[T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”).

187. James A. Henderson, Jr., *Judicial Review of Manufacturers’ Conscious Design Choice: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1539–41 (1973) (discussing struggles of polycentricity in products liability). But see *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (providing Circuit Judge Kozinski’s analysis on remand).

188. Aaron D. Twerski, *Seizing the Middle Ground Between Rules and Standards in Design Defect Litigation: Advancing Directed Verdict Practice in the Law of Torts*, 57 N.Y.U. L. REV. 521, 544–47 (1982) (addressing some of the issues associated with defining “design defect”).

189. *Defective and Unreasonably Dangerous Condition of Product*, AM. L. PRODS. LIAB. 3D § 17:5 (2016).

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

“defective product” is liable for harm to persons *caused* by the defect.¹⁹⁵ Thus, a “defect” and causation are required under the Restatements.¹⁹⁶ The Restatements classify a product as “defective in design,” “when the *foreseeable risks of harm* posed by the product could have been reduced or avoided by the adoption of a *reasonable alternative design* . . . and the omission of the alternative design renders the product *not reasonably safe*.”¹⁹⁷

No matter the definition, expert testimony will be required to meet most any standard where risk-utility balancing (including reasonableness), proximate causation (including foreseeability), or reasonable alternative design comes into play. To be defective, the risks of harm must be foreseeable such that: “[o]nce the plaintiff establishes that the product was put to a *reasonably foreseeable use*, physical risks of injury are generally known or reasonably knowable by experts in the field.”¹⁹⁸ A degree of knowledge that includes the common knowledge attributable to experts in the field is imputable to medical device manufacturers.¹⁹⁹

Many states require proof from the plaintiff that a device is not reasonably safe by requiring the proposal of a safer “reasonable alternative design” (or comparable term) that is technologically feasible (and in some states, economically feasible).²⁰⁰ An orthopaedic expert will be required to propose a reasonable alternative design in almost any orthopaedic implant design defect case.

195. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (AM. LAW INST. 1998) (emphasis added).

196. *Id.*

197. *Id.* § 2 (emphasis added).

198. *Id.* § 2 cmt. m (emphasis added).

199. *Curtis, Collins & Holbrook Co. v. United States*, 262 U.S. 215, 222 (1923) (“The general rule is that a principal is charged with the knowledge of the agent acquired by the agent in the course of the principal’s business.”); RESTATEMENT (THIRD) OF AGENCY § 5.03 (AM. LAW INST. 2006); RESTATEMENT (SECOND) OF AGENCY § 272 (AM. LAW INST. 1958); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. m (AM. LAW INST. 1998); A.G.S., Annotation, *Duty of Manufacturer or Seller to Warn of Latent Dangers Incident to Article as a Class, as Distinguished from Duty with Respect to Defects in Particular Article*, 86 A.L.R. 947, Art. 2, Cumulative Supp. (1930) (explaining the imputation, and identifying cases where the duty was breached).

200. See, e.g., *Voss v. Black & Decker Mfg.*, 450 N.E.2d 204, 209 (N.Y. 1983) (accepting a plaintiff’s showing of a safer design for a circular power saw).

When “reasonableness” enters the equation, courts often turn to risk-utility balancing similar to negligence claims, even in strict products liability cases, so familiar tests such as Judge Learned Hand’s $B < PL$ may come into play.²⁰¹ Again, experts are vital to assessing all of the factors in the famous equation from *Carroll Towing*. Professor John Wade identified seven factors used by many jurisdictions to perform risk-utility evaluations: (1) “usefulness and desirability of the product—its utility to the user and public as a whole,” (2) “safety aspects of the product,” including likelihood of resulting injury and seriousness of any injury, (3) “availability of a substitute product” to meet the “same need and not be as unsafe,” (4) economic feasibility of eliminating the device’s unsafe character, (5) “user’s ability to avoid the danger by the exercise of care in the use of the product,” (6) “user’s anticipated awareness of the dangers inherent in the product,” and (7) “feasibility . . . of the manufacturer . . . spreading the loss by setting the price of the product or carrying liability insurance.”²⁰² Expert testimony will be important in meeting all of Wade’s factors, but especially safety aspects (#2), availability of a substitute product (#3), economic feasibility of eliminating unsafe character (#4), and feasibility of loss spreading (#7).²⁰³

201. See *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947) (establishing the $B < PL$ equation); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2.

202. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837–38 (1973). Wade’s factors have been adopted by many jurisdictions. See, e.g., *LaBelle v. Philip Morris, Inc.*, 243 F. Supp. 2d 508, 515 n.4 (D. S.C. 2001); *Dart v. Wiebe Mfg., Inc.*, 709 P.2d 876, 879–80 (Ariz. 1985) (en banc); *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 n.10 (Colo. 1992); *Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1330 n.10 (Conn. 1997); *Tabieros v. Clark Equipment Co.*, 944 P.2d 1279, 1309 (Haw. 1997); *Wortel v. Somerset Indus., Inc.*, 770 N.E.2d 1211, 1218 (Ill. App. Ct. 2002); *Banks v. Iron Hustler Corp.*, 475 A.2d 1243, 1252 n.3 (Md. Ct. Spec. App. 1984); *Nunnally v. R.J. Reynolds Tobacco Co.*, 869 So.2d 373, 379–80 (Miss. 2004); *Duke v. Gulf & Western Mfg. Co.*, 660 S.W.2d 404, 411–12 (Mo. Ct. App. 1983); *Johansen v. Makita U.S.A., Inc.*, 607 A.2d 637, 642–43 (N.J. 1992); *Duran v. Gen. Motors Corp.*, 688 P.2d 779, 784 (N.M. Ct. App. 1983); *Rainbow v. Albert Elia Bldg. Co.*, 79 A.D.2d 287, 291 n.2, 436 N.Y.S.2d 480, 483 n.2 (N.Y. App. Div. 1981), *aff’d*, 434 N.E.2d 1345 (N.Y. 1982); *Roach v. Kononen*, 525 P.2d 125, 128–29 (Or. 1974); *Phatak v. United Chair Co.*, 756 A.2d 690, 694 (Pa. Super. Ct. 2000).

203. See Wade, *supra* note 202, at 638–40. The author elucidates how the technical nature of design defect cases often require technical expertise to

Thus, in order to prove design defect, experts are vital to both sides in proving elements of their cases, in all jurisdictions, and in almost every case. As noted by the Restatements, “[f]or justice to be achieved,” the definition of design defect “should not be construed to create *artificial and unreasonable barriers to recovery*.”²⁰⁴ Prejudicial *Daubert* rulings eliminating vital experts on either side have the potential to create exactly such an unjust barrier.

2. *Daubert*’s Framework as a Possible Artificial and Unreasonable Barrier to Recovery

Since most orthopaedic device companies are located in Warsaw, Indiana,²⁰⁵ complete diversity removal to federal court is often an option, and seems to be the preference for orthopaedic device manufacturers in states where *Daubert* has not been adopted.²⁰⁶ *Daubert* was supposed to allow juries to hear well-reasoned, novel scientific evidence replacing Frye’s test that allowed only evidence with “general acceptance in [a] particular field.”²⁰⁷ The judge’s role is supposed to be that of a gatekeeper to “exclude unreliable expert testimony” and keep “junk science” out of the courtroom.²⁰⁸ The jury is charged with assessing the “weight and credibility” of relevant evidence.²⁰⁹

Daubert outlined a flexible, non-exclusive checklist for trial judges to use in the assessment of the admissibility of expert

evaluate dangerousness of a product. In order to properly evaluate whether the defect could be overcome by reasonable means and cost, it stands to reason an expert is necessary.

204. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f (emphasis added).

205. See Barnaby Feder, *In the Land of the Orthopaedic Implant*, N.Y. TIMES (Sept. 18, 1994), <http://www.nytimes.com/1994/09/18/business/in-the-land-of-the-orthopaedic-implant.html>.

206. See, e.g., *Shelton v. DePuy Orthopaedics, Inc.*, No. CV 11–08082 DDP (JCGx), No. CV 11–08082 DDP JCGX, 2011 WL 6001630, at *2 (C.D. Cal. 2011).

207. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

208. FED. R. EVID. 702, Committee Notes on Rules—2000 Amendment, <http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title28a-node216-article7-rule702&num=0&edition=prelim> [hereinafter FRE 702 Committee Notes]; see *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995); Hein, *supra* note 185; see also *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 153 (1997) (discussing *Daubert*’s ‘junk science’ target); *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579, 589–95 (1993); 985 Assoc., Ltd. v. Daewoo Elecs. Am., Inc., 945 A.2d 381, 384 (Vt. 2008).

209. FED. R. EVID. 104(e).

testimony under Federal Rules of Evidence Rule 702, including (1) whether the expert's technique or theory has been objectively tested, (2) whether the expert's technique or theory has been subject to peer review and publication, (3) whether there is a known rate of error of the expert's technique or theory, (4) whether there are standards and controls involved in the expert's technique or theory, and (5) whether the expert's technique or theory has been generally accepted in the scientific community.²¹⁰ The court did not intend for these factors to be dispositive or conclusive.²¹¹ Other courts have added additional factors to the analysis including (1) whether the experts have "developed their opinions expressly for purposes of testifying,"²¹² (2) whether there is "too great an analytical gap between the data and the opinion proffered,"²¹³ (3) whether the expert has accounted for "obvious alternative explanations" adequately,²¹⁴ (4) whether the expert is being as careful in his paid litigation consulting as he would be in his regular professional work,²¹⁵ and (5) whether the expert's field of expertise is known for reliable results in the area of the expert's testimony.²¹⁶

Daubert is not supposed to empower trial court judges to determine which scientific theory or conclusion is best; instead, it demands that the judge focus on the principles and methodology employed by the expert—"not on the conclusions they generate."²¹⁷ Overall, the "rejection of expert testimony is

210. *Daubert*, 509 U.S. at 589–95; FRE 702 Committee Notes, *supra* note 208.

211. See FRE 702 Committee Notes, *supra* note 208 ("*Daubert* itself emphasized that the factors were neither exclusive nor dispositive.>").

212. See *Daubert*, 43 F.3d at 1317 (cautioning that courts "may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office").

213. See *Gen. Elec. Co.*, 522 U.S. at 146.

214. See *Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (9th Cir. 1994) (citing *Daubert* for the proposition that experts should not "neglect[] to investigate any other possible causes of plaintiffs' injuries").

215. See *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997).

216. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999); *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988).

217. FRE 702 Committee Notes, *supra* note 208; *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579, 595 (1993). See also *Mass. Mut. Life Ins. v. Residential Funding Co.*, 989 F. Supp. 2d 165 (D. Mass. 2013); *Amorgianos v.*

the exception rather than the rule.”²¹⁸ The trial judge’s role as “gatekeeper is *not* intended to serve as a replacement for the adversary system.”²¹⁹ Again, it is the jury that is charged with assessing the “weight and credibility” of the evidence.²²⁰

The *Daubert* Court emphasized that “*vigorous cross-examination*, presentation of *contrary evidence*, and *careful instruction on the burden of proof* are the traditional and appropriate means of attacking shaky but admissible evidence.”²²¹ Contradictory opinions should both often be deemed reliable.²²² Proponents of experts only have to show by a preponderance of the evidence that the expert’s opinion is reliable, NOT that it is correct.²²³ In some cases, “*experience alone—or experience in combination with other knowledge, skill, training, or education*” may be sufficient for the expert’s opinion to be reliable—“Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.”²²⁴

Daubert’s judicial charge has challenged federal judges from the beginning. The Ninth Circuit, on *Daubert* remand, considered their lot an “uncomfortable position” in a “Brave New World” describing its new gatekeeper role as “complex and daunting” where “though [it was] largely untrained in science and certainly no match for any of the witnesses whose testimony [it was] reviewing, it [was the Court’s] responsibility to determine whether those experts’ proposed testimony amount[ed] to ‘scientific knowledge,’ constitut[ed] ‘good science,’ and was ‘derived by the scientific method.’”²²⁵ The court recognized that the cutting edge of science is “where fact

National R.R. Passenger Corp., 303 F.3d 256 (2d Cir. 2002); *Brumley v. Pfizer, Inc.*, 200 F.R.D. 596 (S.D. Tex. 2001).

218. FRE 702 Committee Notes, *supra* note 208.

219. *United States v. 14.38 Acres of Land Situated in Leflore Cty.*, 80 F.3d 1074, 1078 (5th Cir. 1996) (emphasis added).

220. FED. R. EVID. 104(e).

221. *Daubert*, 509 U.S. at 595 (1993) (emphasis added).

222. *See, e.g., Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 160 (3d Cir. 1999).

223. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994) (“A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect”).

224. FRE 702 Committee Notes, *supra* note 208 (emphasis added); *see, e.g., United States v. Jones*, 107 F.3d 1147 (6th Cir. 1997); *Tassin v. Sears Roebuck*, 946 F. Supp. 1241, 1248 (M.D. La. 1996).

225. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315–16 (9th Cir. 1995).

meets theory and certainty dissolves into probability” and seemed reluctant to “take a deep breath and proceed with [the] heady task” at hand.²²⁶ Thus, it is understandable that federal judges might struggle to handle complex orthopaedic implant design cases properly.

Since *Daubert*, *in limine* challenges have increased, “primarily driven by a significant increase in the number of *in limine* challenges raised against plaintiff expert witnesses.”²²⁷ One-sided interpretations of *Daubert* by federal judges to the detriment of plaintiffs can have a “chilling effect” on the availability of fair jury trials in complex areas of litigation like orthopaedic implant design—especially if the judges are prejudicially allowing defense experts while simultaneously prejudicially excluding plaintiff experts.²²⁸ It is therefore particularly important that federal judges properly distinguish between unreliable science, reliable science, and marketing tactics in order to justly adjudicate orthopaedic design defect cases.

C. *DAUBERT* RULINGS OFTEN DECISIVELY FAVOR THE ORTHOPAEDIC INDUSTRY: A CLOSER LOOK AT ORTHOPAEDIC DESIGN DEFECT CASES

Under Rule 702 and *Daubert*, the trial judge’s role is to “exclude unreliable expert testimony.”²²⁹ Prejudicial tendencies in pre-trial *Daubert* rulings on admissibility of expert testimony likely determine the outcomes of complex orthopaedic design defect litigation and may lead to an artificial and unreasonable barrier to recovery for injured patients.²³⁰ Judges tend to prejudicially allow defense experts while simultaneously prejudicially excluding plaintiff experts in orthopaedic design defect cases. This may be due to (1) improperly interpreting the reliability of scientific testimony by

226. *Id.*

227. David M. Flores et al., *Examining the Effects of the Daubert Trilogy on Expert Evidence Practices in Federal Civil Court: An Empirical Analysis*, 34 S. ILL. U. L. J. 533, 562 (2010).

228. See Kanner & Casey, *supra* note 101, at 317–18 (identifying a study where “the frequency of summary judgment grants against plaintiffs had increased”).

229. FRE 702 Committee Notes, *supra* note 208; see also *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579, 592–93 (1993).

230. See, e.g., *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 4880953 (N.D. Ill. Aug. 13, 2015).

admitting experts with million dollar conflicts of interest while excluding experts paid thousands to formulate answers to novel questions raised by new, untested implants, (2) judges relying too heavily on flawed epidemiology testimony while discounting experience testimony, and (3) judges giving prejudicial deference to industry polycentricity theories while ignoring industry's double standard on polycentricity in the underlying "substantial equivalence" determinations.²³¹

1. Improper Interpretation of Reliability: Allowing Conflict of Interest Testimony While Disfavoring Trial Prep Testimony

Judicial gatekeepers tend to ignore unreliability issues haunting defense experts with million dollar conflicts of interest affecting their research, while they aggressively disfavor plaintiff experts who performed their research in preparation for trial for a few thousand dollars.²³²

a. Favoring Testimony from Defense Experts with Million Dollar Conflicts

Conflicts of interest affect reliability of expert testimony such that some experts with clear conflicts of interest should be excluded under *Daubert*, but there appears to be a tendency for these conflicts to be overlooked by the gatekeepers.²³³ Conflicts of interest—especially royalties and consultant or employee status—have been shown to lead to positive outcome bias reporting in orthopaedic research.²³⁴ One study reported the statistically significant finding that orthopaedic surgeons with royalties, stock options, or consulting/employee contracts were more likely to report positive outcomes in their studies than

231. See discussion *infra* Part III.C Sections 1, 2, and 3; see also *Sumner v. Biomet*, 434 F. App'x 834 (11th Cir. 2011) (excluding experts with budgets only in the thousands); *In re Zimmer*, 2015 WL 4880953 (discussing admission of experts with million-dollar conflicts of interest).

232. See discussion *infra* Sections 1.a, 1.b; see also *Sumner*, 434 F. App'x at 834 (disfavoring low-budget research testimony); *In re Zimmer*, 2015 WL 4880953 (favoring million-dollar conflicts of interest).

233. See, e.g., *In re Zimmer*, 2015 WL 4880953.

234. Kanu Okike et al., *Conflict of Interest in Orthopaedic Research: An Association Between Findings and Funding in Scientific Presentations*, 89 J. BONE & JOINT SURGERY AM. 608, 608–13 (2007).

those without those conflicts of interest.²³⁵ Specifically, 100% of the surgeons with stock options, 98.4% of those with royalties, and 97.8% of those who were employees of implant companies reported positive outcomes.²³⁶

Self-preservation, loyalty, and emotional connections with pet projects can lead to unreliable testimony from experts with conflicts of interest—especially large financial conflicts like royalties, stock options, and employment contracts.²³⁷ Design contracts and royalties are lucrative business for the researchers—with some consulting surgeons making millions—so “[f]ew researchers today will risk alienating the hands that feed them.”²³⁸ Testifying against the industry in a lawsuit certainly carries a substantial risk of alienating the device makers in a small, highly-profitable environment where eight companies have consistently controlled 95% of the market.²³⁹ In addition, industry experts may feel a particular loyalty to protect the defendant company who has directly supported them, their research, and their pet projects over the years²⁴⁰—with new devices becoming like their own newborn baby . . . in which it is subjectively impossible for the parent to see an ugly flaw.

The Zimmer Flex bellwether case outlined earlier is a good example of apparently unnoticed significant conflicts of interest that could affect the reliability of the experts’ testimony. In that case, the judge did a well-reasoned (for a non-scientist, non-orthopaedist jurist) analysis of the experts’ testimony proffered by both sides.²⁴¹ She allowed two experts for the

235. *Id.* at 609; see also Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454–65 (2003).

236. Okike et al., *supra* note 234, at 611.

237. Bekelman et al., *supra* note 235, at 463.

238. SARMIENTO, *supra* note 11, at 278.

239. See ORTHOKNOW, *supra* note 3, at 4.

240. Barry Meier, *Doctors Who Don’t Speak Out*, N.Y. TIMES (Feb. 17, 2013), <http://www.nytimes.com/2013/02/17/sunday-review/the-hip-replacement-case-shows-why-doctors-often-remain-silent.html>.

241. See, e.g., *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5095727 (N.D. Ill. Aug. 27, 2015); *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 4880953 (N.D. Ill. Aug. 13, 2015).

defense with obvious conflicts of interest that received no mention in her analysis of reliability.²⁴²

Specifically, over the plaintiff's objection, the judge allowed Dr. Darryl D'Lima to testify and present a "computer simulation technique to model the real-world behavior of physical structures."²⁴³ D'Lima collaborates with Zimmer on total knee design²⁴⁴ and listed himself as a "Principal Investigator" for Zimmer in his online public Conflict of Interest Disclosure for the orthopaedic journal, *Arthroplasty*, in October 2014.²⁴⁵ Not only was D'Lima—a collaborator, Principal Investigator, and agent of the Defendant—allowed to offer opinion testimony, he was allowed to present a computer simulation of knee kinematics during flexion without a single mention of his conflicts of interest in the judicial analysis.²⁴⁶ If D'Lima received royalties, stock options, or employment from Zimmer, then the positive outcome bias reported in the orthopaedic literature for such researchers should have been given considerable weight in the *Daubert* calculus for "unreliable expert testimony"—especially considering his testimony based on theoretical computer models—under Rule 702.²⁴⁷

A second expert with an obvious conflict of interest was likewise allowed to testify in the Zimmer Flex case. Dr. Timothy Wright disclosed himself as a "Paid Consultant" for Zimmer as noted in his online public Conflict of Interest Statement for the journal, *Arthroplasty*, in March 2015.²⁴⁸ The judge apparently allowed Dr. Wright to give his analysis of the orthopaedic literature to the jury as kind of epidemiology study

242. See *In re Zimmer*, 2015 WL 4880953.

243. *Id.* at *2; see also Baker, *supra* note 177, at *6.

244. See Darryl D'Lima et al., *In Vivo Knee Forces During Recreation and Exercise After Knee Arthroplasty*, 466 CLINICAL ORTHOPAEDICS & RELATED RES. 2605, 2606 (2008).

245. Darryl D'Lima, *Conflict of Interest Statement*, J. ARTHROPLASTY (Oct. 14, 2014), <http://www.arthroplastyjournal.org/cms/attachment/2034778135/2050119221/mmc1.pdf>.

246. *In re Zimmer*, 2015 WL 4880953, at *2; see also Baker, *supra* note 177, at *1–2.

247. FRE 702 Committee Notes, *supra* note 208.

248. Timothy Wright, *Conflict of Interest Statement*, J. ARTHROPLASTY (Mar. 7, 2015), <http://www.arthroplastyjournal.org/cms/attachment/2045747296/2057042939/mmc1.pdf>.

relating to the Zimmer Flex knees.²⁴⁹ In her thirty-four page *Daubert* analysis of Wright and some other experts, conflict of interest was not mentioned in the reliability assessment.²⁵⁰

The orthopaedic peer-reviewed journal editors consider it “*essential* that an author disclose *potential* conflicts of interest,” and the court system should do likewise if it hopes to properly determine reliability.²⁵¹ Some paid consultants make millions of dollars.²⁵² The American Academy of Orthopaedic Surgeons has a “Mandatory Disclosure Policy” for educational programs, in place since 2011, requiring presenters to disclose “relevant potentially conflicting interests or commercial relationships.”²⁵³ Likewise, the Journal of the American Academy of Orthopaedic Surgeons along with seventeen other peer-reviewed orthopaedic journals issued a consensus statement saying readers of medical journals are “entitled to a full disclosure of all financial conflicts of interest of the authors of those articles”²⁵⁴ and agreeing to use the universal disclosure form developed by the International Committee of Medical Journal Editors (ICMJE).²⁵⁵

249. In re Zimmer NexGen Knee Implant Prods. Liab. Litig., No. 11-C-5468, 2015 WL 5095727, at *3 (N.D. Ill. Aug. 27, 2015) (“Dr. Wright reviews six studies and data from the Australian Orthopaedic Association’s National Joint Registry, and opines that, if the design were defective, consistent failure of the device would manifest in the clinical evidence.”).

250. See *id.*

251. Vernon T. Tolo, Editorial, *Orthopaedic Journals and Conflicts of Interest*, 93 J. BONE & JOINT SURGERY 2145 (2011) (emphasis added), <http://jbjs.org/content/jbjsam/93/23/2145.full.pdf>.

252. See, e.g., Meier, *supra* note 154 (reporting compensation for Dr. Richard Berger at more than \$8 million over a decade); see also Tolo *infra* note 256, at 1 (mentioning thirty-two orthopaedic surgeons who were “known to have been paid over \$1 million” during the year prior to publication of their article); DORR ARTHRITIS INST., *Dr. Lawrence Dorr*, <http://www.dorrarthritisinstitute.org/dorr.html> (last visited Sept. 7, 2016) (noting Dr. Dorr has been paid “millions of dollars” in royalties for his devices); Bruera, *supra* note 76, at 38 (noting the surgeons mentioned “received millions of dollars in royalties”).

253. AAOS *Mandatory Disclosure Policy*, AAOS, <http://www.aaos.org/CustomTemplates/Content.aspx?id=5627> (last visited Sept. 20, 2016).

254. Tolo, *supra* note 251, at 2145.

255. See ICMJE, *Conflicts of Interest*, INT’L COMM. MED. J. DIRS., <http://www.icmje.org/conflicts-of-interest/> (scroll down until you see blue download button; then click download to access form) (last visited Sept. 7, 2016).

If readers of journals are “entitled to a full disclosure,” shouldn’t judges and juries be similarly entitled? Even with disclosure policies in place in 2010, compliance was still an issue; one study showed “a 46% nondisclosure rate of conflicts of interest among thirty-two orthopaedic surgeons . . . who were known to have been paid over \$1 million” in the year before publication of the article.²⁵⁶

Courts should require conflict of interest disclosure statements similar to those used for orthopaedic journals from all experts. Those conflicts should be taken into account by the judicial gatekeeper when deciding whether the testimony is reliable under *Daubert*, particularly considering the well-documented positive outcome bias among conflicted researchers.

b. Disfavoring Testimony from Plaintiffs’ Experts with Thousand Dollar Conflicts

Paradoxically, the courts have flipped the conflict of interest argument against plaintiffs’ experts. From the outset, courts have concluded that experts making several thousand dollars to prepare research in preparation for trial have an unacceptable conflict of interest, while concluding that experts making millions of dollars preparing research to support their own products, royalties, stock options, and employee contracts do not have an inadmissible conflict. Indeed the Ninth Circuit, on *Daubert* remand, indicated that a factor especially important to the analysis was whether the experts have “developed their opinions expressly for purposes of testifying” and whether the expert “has conducted [his/her research] independent of the litigation.”²⁵⁷

The Court assumed that “independent research carries its own indicia of reliability, as it is conducted . . . in the usual course of business and must normally satisfy . . . standards to

256. Vernon T. Tolo, Editorial, *Interest in Conflicts*, 93 J. BONE JOINT & SURGERY AM. 1 (2011) (citing Susan Chimonas et al., *From Disclosure to Transparency: The Use of Company Payment Data*, 171 ARCHIVES INTERNAL MED. 81 (2010)); see also Kanu Okike et al., *Accuracy of Conflict of Interest Disclosures Reported by Physicians*, 361 NEW ENG. J. MED. 1466, 1466–74 (2009).

257. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

attract funding and institutional support.”²⁵⁸ However, in orthopaedic design defect cases, novel issues are often presented by new devices that have never been studied by anyone (so there is no pre-existing research).²⁵⁹ This includes the same defendants who are making millions from the sale of the device, cleared the device via the “substantial equivalence” pathway, and will often roll out a new device before there is time to figure out any problems with the old device.²⁶⁰ Further, research performed by paid consultants for the device manufacturer is not “independent,” even if done before the litigation begins.

The metal-on-metal (MoM) hip cases are an excellent example of the novel questions posed by design defect questions and the enormous dilemma plaintiff’s experts face in attacking an alleged defect for an orthopaedic implant. Metal debris around the hip and elevated metal ion levels in the blood stream were simply something that had not been previously seen nor studied. In a MoM hip case filed in 2008 (before the FDA got involved and before the recalls), the plaintiff hired a metallurgist who was a professor of material science at Rice University in Houston with a PhD in metallurgy to testify.²⁶¹ The metallurgist tried to explain the phenomenon of metal debris in a patient’s hip visible on x-ray four months post-op by looking at the surfaces of the metal-on-metal contact with an electron microscope to find a source for the visible debris at a time when companies were denying there was a problem with MoM hips.²⁶²

After studying the implants retrieved from the plaintiff’s hip with an electron microscope, the metallurgist testified that “by some unknown means, particles embedded in the prosthesis ejected from the prosthesis . . . ultimately leading to failure of the device,” and postulated that the metal particles were being “ejected” from the metal-on-metal surface due to inhomogeneity

258. *Id.*

259. *See* SARMIENTO, *supra* note 11, at 285–86, and accompanying text.

260. *Id.*

261. *See* Sumner v. Biomet, Inc., No. 7:08-CV-00098-HL, 2010 WL 4272341 (M.D. Ga. 2010) (Affidavit of Rex B. McLellan, PhD).

262. Sumner v. Biomet, Inc., No. 7:08-CV-00098-HL, 2010 WL 4736320, at *1 (M.D. Ga. Nov. 16, 2010), *aff’d*, 434 F. App’x 834 (11th Cir. 2011) (“Dr. McLellan stated that the ball of the prosthesis was severely gouged and scratched, and that there were multiple areas where blocks of metal had exited the surface.”).

in the chemistry of the cobalt/chromium surfaces. This type of inhomogeneity is one of the current theories as to why some MoM hips allegedly failed.²⁶³

Under the first *Daubert* factor, the trial judge noted that the expert admitted there was no way of testing his theory that the metal particles were being ejected from the device—a strike against reliability.²⁶⁴ But how could a plaintiff's expert even get access to patients to test his theory? He would need access to multiple patients who were willing to have blood tests drawn and tests done²⁶⁵ that no one else was doing at a time when a new device was being introduced with minimum available information.

Under the second *Daubert* factor, the judge noted that the expert's technique had never been subjected to peer review nor publication, and that he had never been involved in a prior case where this mode of failure was described—a second strike against reliability.²⁶⁶ But again, this was new technology, with a completely new mode of failure, caused by a device that had minimal clinical background propping it up.²⁶⁷ How could he possibly have been involved in such a prior case unless he was a consultant of the manufacturer working on research for the company?

Under the third *Daubert* factor, there was “no known or potential error rate” for his methodology, because the MoM technology and application of electron microscopy to the problem was a novel one—strike three.²⁶⁸

Finally, under the fourth *Daubert* factor, regarding whether his technique or theory was generally accepted in the scientific community, the court called strike four.²⁶⁹ The

263. *Id.* at *4–6.

264. *Id.* at *4 (“Not having tested his own theory weighs greatly against the finding of reliability.”).

265. *See, e.g.,* FDA, *Metal-on-Metal Hip Implants: Concerns About Metal-on-Metal Hip Implants*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241604.htm> (last updated Apr. 10, 2015) (discussing some of the diagnostic measures required to identify problems with MoM joint replacements).

266. *See Sumner*, 2010 WL 4736320, at *4 (“Dr. McLellan has failed to present any evidence of any peer review of his opinions or theory . . .”).

267. *See, e.g., id.* at *3.

268. *Id.* at *5.

269. *Id.*

plaintiff's metallurgist "testified that no scientist, metallurgist, physician, or anyone else in the world has ever espoused the opinion that inhomogeneities in the surface of a device can lead to ejection of metal fragments," so this novel idea was not generally accepted in the scientific community.²⁷⁰

The metallurgist stated that "the particle ejection theory relates to a unique problem associated with a specific device," and that "it has not been considered before by the scientific community."²⁷¹ The gatekeeper's response was that "the Court has a problem with the fact that [plaintiff's expert] never bothered to test the theory or publish anything about the theory," adding "[i]t is quite difficult for other scientists to peer review a theory if the creator of the theory does not attempt to test it or publish anything about it."²⁷² Peer-reviewed articles take years of experimentation and sometimes additional years to publish.²⁷³ Where novel medical devices are involved statutes of limitation have run, and devices may have already been replaced with the next device by the time any peer-reviewed literature can be published on such a topic. This would be true even if the researcher could gain access to the resources and patients to do the research, which they likely cannot.

The trial judge excluded the metallurgist's testimony and granted summary judgment for the device manufacturer.²⁷⁴ The court emphasized the importance of the "fact that [the metallurgist] developed the particle ejection theory expressly for the purposes of this case."²⁷⁵ The appellate court affirmed under the abuse of discretion standard of *Daubert*.²⁷⁶ If not for the Joint Registry Databases in the U.K. and Australia,²⁷⁷ it is likely that MoM hips would have continued to thrive much

270. *Id.*

271. *Id.*

272. *Id.*

273. *See, e.g.,* Caton et al., *supra* note 85. This study describes outcomes for patients who received hip replacements twenty-five years prior. Some data simply cannot follow a litigation timetable.

274. *Sumner v. Biomet, Inc.*, 434 F. App'x 834 (11th Cir. 2011).

275. *Sumner*, 2010 WL 4736320, at *5.

276. *Sumner*, 434 F. App'x at 841–43; *Inadmissible Testimony Dooms Suit over Hip Implant*, 11th Circuit Says, 18 WESTLAW J. MED. DEVICES 2 (2011).

277. *See* NAT'L JOINT REGISTRY FOR ENG. AND WALES, cited in parenthetical *supra* note 109.

longer in the United States, despite plaintiffs seeking relief from the court system.

Judges should allow the jury to hear testimony from qualified plaintiffs experts without regard to whether the research was done in preparation for trial in novel orthopaedic design defect cases because these issues will rarely be addressed in the peer-reviewed literature until well past statutes of limitation. Similarly, the significant positive outcome bias in orthopaedic literature makes it very unlikely early negative studies will be published.²⁷⁸ The plaintiff should at least be given a fair shot to present reasonable theories of failure to the jury in these complex, novel cases on the cutting edge of medicine.²⁷⁹ The jury can then decide how much weight and credibility to give the expert's testimony based upon impeachment evidence presented at trial.²⁸⁰

2. Overreliance on Flawed Epidemiology and Under-Reliance on Experience Testimony

Judicial gatekeepers tend to prejudicially favor epidemiological reports that inherently benefit the device industry and disfavor experience testimony that might benefit the plaintiff.

a. Prejudicial Admission of Flawed Epidemiology Favoring Industry

Judges overestimate the reliability of epidemiology studies in the orthopaedic implant industry to the detriment of plaintiffs. Epidemiology has been described as “a field that concerns itself with finding the causal nexus between external factors and disease” and “is generally considered to be the best evidence of causation in toxic tort actions.”²⁸¹ Although courts recognize “there is not a precise fit between science and legal burdens of proof,” most courts are “persuaded that *properly designed and executed* epidemiological studies may be part of the evidence supporting causation in a toxic tort case.”²⁸² Some

278. See discussion *infra* Section C.2.a.

279. Cf. *Sumner*, 2010 WL 4736320, at *4–6 (rejecting the plaintiff's expert's report on a motion to exclude).

280. FRE 702 Committee Notes, *supra* note 208.

281. *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002).

282. See, e.g., *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 717 (Tex. 1997) (emphasis added).

courts even consider epidemiological evidence to be “indispensable” where direct proof of causation is lacking in toxic tort cases.²⁸³

But what if the orthopaedic literature is biased to the point that epidemiology will always either be positive or nonexistent? Sources for systematic flaws in the orthopaedic literature in favor of industry include (1) systemic positive outcome bias, (2) biased authors, and (3) the fact that the skill level of the authors does not match skill level of the foreseeable end users of the devices at issue.²⁸⁴

First, the orthopaedic literature is tainted with an inherent “positive outcome bias” that judges should take into account before becoming too enamored with orthopaedic device epidemiology studies.²⁸⁵ The unrecognized introduction of positive outcome bias attributed to systematic reviews—like epidemiology studies—is considered by some to present “a *severe challenge to patient safety*.”²⁸⁶ Basically, positive studies get disproportionately published in the surgical literature, while negative and neutral studies mostly go unpublished.²⁸⁷ A “publication bias” toward publishing positive data while leaving negative studies unpublished systematically overestimates the clinical relevance of surgical treatments by disregarding the negative and neutral studies that are not being published.²⁸⁸ Specifically, one comprehensive seven-year study found that 74% of published original papers reported positive outcomes, whereas only 17% reported negative outcomes, and only 9% reported neutral outcomes.²⁸⁹ One

283. See, e.g., *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1128 (2d Cir. 1995).

284. See, e.g., Erik A. Hasenboehler, *Bias Towards Publishing Positive Results in Orthopaedic and General Surgery: A Patient Safety Issue?*, 1 PATIENT SAFETY SURGERY art. no. 4 (2007), <http://pssjournal.biomedcentral.com/articles/10.1186/1754-9493-1-4>; Meier, *supra* note 240.

285. Hasenboehler, *supra* note 284, at 2.

286. *Id.* (emphasis added); see also Mohit Bhandari, *3rd Meta-Analyses in Orthopaedic Surgery: A Systematic Review of Their Methodologies*, 83 J. BONE JOINT SURGERY AM. 15–24 (2001); David Moher, *Epidemiology and Reporting Characteristics of Systematic Reviews*, 4 PLOS MED. 447, 447–55 (2007).

287. Hasenboehler, *supra* note 284, at 3–4.

288. *Id.* at 4 (“[T]rials with ‘significant’ results were more likely to be published than studies with ‘non-significant’ data, by an adjusted odds-ratio of 12.30.”).

289. *Id.* at 4 fig.2.

estimate is that 85% of orthopaedic epidemiology studies “may assert biased conclusions.”²⁹⁰

In addition, the underlying studies in the epidemiology studies are generally weak. In the orthopaedic literature, only 15% of systematic reviews were found to be methodologically rigorous.²⁹¹ Good research is apparently the exception rather than the rule. Only 11.3% of the orthopaedic literature used the most reliable level of evidence (Level 1) and only 3% of orthopaedic articles were randomized, controlled trials (the gold standard for clinical research).²⁹²

So why, other than the obvious financial conflicts of interest of some authors, is there such a high “positive outcome bias” in orthopaedic epidemiology studies? Although doctors have an “ethical obligation to warn their peers” and patients about bad devices, “they often do not do so.”²⁹³ Harlan Krumholz, a professor at Yale School of Medicine, says “[q]uestioning the status quo in medicine is not easy.”²⁹⁴ “The standard in the medical community is *not* to report,” said one doctor who reported a defective heart device.²⁹⁵ Doctors may fear being sued or being blamed for bad outcomes—a fear that may be well founded based on Dr. Berger’s experience with the Zimmer Flex knee discussed above.²⁹⁶

Berger is far from alone in being blamed for poor outcomes related to an orthopaedic device. Two years before the ASR MoM hip recall, a British physician—Dr. Antoni Nargol—had a similar experience when he approached DePuy about problems his patients were having with the now recalled device.²⁹⁷ Nargol was told by the company that he seemed to be the only doctor having problems and that there were “no other problems,” so he never sounded a public alarm.²⁹⁸ Another physician to be discussed below, Dr. Lawrence Dorr, likewise

290. Harman Chaudhry et al., *How Good Is the Orthopaedic Literature?*, 42 INDIAN J. ORTHOPAEDICS 144, 144–49 (2008).

291. *Id.*

292. *Id.*

293. Meier, *supra* note 240.

294. *Id.*

295. *Id.* (emphasis added).

296. *See id.*

297. *Id.*

298. *Id.*

was blamed when he reported problems with a device to the company.²⁹⁹

Because 75%–85% of orthopaedic studies will report positive outcomes, only 15%–25% will be neutral or negative; thus, there is an overwhelming likelihood that any epidemiology study that combines these underlying studies will come up with a positive outcome in favor of almost any new device.³⁰⁰ When you add the factors below, it is a virtual certainty that epidemiology will favor the defense whether the device is ultimately defective or not. Therefore, judges should give extra weight to articles reporting negative or neutral findings because they likely represent an underreported, under-published experience.

Second, in addition to “positive outcome bias” that is inherent in the orthopaedic literature, the industry gets an additional boost because its own surgeons often write much of the early literature regarding new devices—devices in which the surgeon is often financially vested with royalties, consulting fees, and stock options dependent upon the success of the implant about which they are writing.³⁰¹ The pressures and incentives can be huge. For example, when Dr. Berger, the Zimmer Flex surgeon mentioned above, published his early data regarding minimally invasive surgery, the Zimmer chairman and CEO stated in a press release at the time, “[w]e are clearly excited about Dr. Berger’s data.”³⁰² Zimmer’s chief scientific officer praised Berger both as “[having] a very clever set of hands” and for his ability to “innovate surgical techniques.”³⁰³ Berger was featured on ABC’s World News Tonight, trained hundreds of surgeons on Zimmer’s behalf, performed 1000 total hips and knees per year, and made \$8 million over ten years from Zimmer alone.³⁰⁴ If his initial data

299. *Id.* (reporting that after publishing an open letter to fellow surgeons regarding a medical device, Dr. Dorr “became the subject of a whisper campaign that questioned his skills as a surgeon”).

300. See Chaudhry et al., *supra* note 290 (“Taken together, this suggests that nearly 85% of orthopaedic systematic reviews may assert biased conclusions.”)

301. *Id.* (“Although funding may improve reporting practices, the source of funding always deserves a critical assessment, as industry-funded studies are significantly more likely to be “positive” studies with pro-industry outcomes.”).

302. Meier, *supra* note 154.

303. *Id.*

304. *Id.*

had been negative or neutral on minimally invasive surgery, it seems likely that neither Zimmer nor World News Tonight would have been as interested.

While Berger was willing to walk away from Zimmer over his results with the Flex knee, many surgeons likely would choose not to do so. Some doctors are even willing to publish falsity for prestige, ego, status, or money.³⁰⁵ Two surgeon consultants for DePuy's ASR hip testified that they "received millions of dollars in royalties from sales" and continued to "promote[] the device with orthopedic surgeons . . . despite their knowledge of adverse events and inherent defects in the ASR's design."³⁰⁶ Remember, 100% of the surgeons with stock options, 98.4% of those with royalties, and 97.8% of those who were employees of implant companies reported positive outcomes in their scientific presentations.³⁰⁷ Thus, reliability is unlikely when dealing with studies published by the company's own surgeons, and *Daubert* requires the judge to exclude unreliable testimony.

Epidemiology may have played a role in the Zimmer Flex knee trial outcome. The trial judge admitted the pediatric spine surgeon's epidemiology study along with the paid Zimmer consultant's epidemiology opinions without mentioning any analysis of underlying positive outcome bias nor underlying author bias.³⁰⁸ Today, judges should look at the conflict of interest disclosures for authors of studies used by epidemiologists and eliminate studies written by highly-paid industry surgeons and consultants before the epidemiologist crunches the numbers.

Third, published studies are biased because they are written by "master" surgeons using the new implants in high

305. See, e.g., Brendan Borrel, *A Medical Madoff: Anesthesiologist Faked Data in 21 Studies: A Pioneering Anesthesiologist Has Been Implicated in a Massive Research Fraud That Has Altered the Way Millions of Patients Are Treated for Pain During and After Orthopaedic Surgeries*, SCI. AM. (Mar. 10, 2009), <http://www.scientificamerican.com/article/a-medical-madoff-anesthetes-iologist-faked-data/>.

306. Bruera, *supra* note 76, at 38.

307. Okike et al., *supra* note 234.

308. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 5050214, at *1 (N.D. Ill. Aug. 25, 2015) ("Though the court shares some of Plaintiff's concerns, it ultimately concludes that Dr. Vitale's testimony would assist the jury and will be sufficiently reliable. The motion to bar his testimony will be denied.")

volume practices, whereas design defect law applies to “reasonably foreseeable use” of the product “in light of [its] nature and intended function.”³⁰⁹ Seventy-five percent of total hip replacements are performed by surgeons who do fewer than twenty-five total hip operations per year, and 25% of total knee operations are done by surgeons who perform fewer than *twelve* total knees per year.³¹⁰ Thus, it is reasonably foreseeable that total joint replacements will be implanted by surgeons with considerably less experience and expertise than the “master” surgeons who write the articles and design the implants—the “super experts.”

Yet, implant companies rarely, if ever, publish studies assessing outcomes with their devices in the hands of the average surgeon. The vast majority of orthopaedic procedures in the United States are *not* performed by master, industry-insider surgeons—yet virtually all of the orthopaedic literature is written about those doctors’ patients. By analogy, just because Michael Jordan can score thirty-one points per game does not mean that an average NBA player can do the same. Similarly, just because a gifted “master” surgeon can obtain reasonable outcomes with a new device that he helped design does not mean the average surgeon using the device for the masses will have similar results. The company should have some duty to look into the effectiveness of their design in the hands of those who are most likely to do the majority of the procedures: the average surgeon. At the very least, courts have a duty to recognize the resultant added positive outcome bias, and then interpret epidemiology studies with an appropriate level of skepticism.

In summary, courts should become less enamored with epidemiology because of systemic positive outcome bias, conflicts of interest of the authors of underlying studies, and

309. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2, cmt. m; *Defective and Unreasonably Dangerous Condition of Product*, *supra* note 189, § 17:5.

310. S. Rodriguez-Elizalde et al., *Provider Volumes and Surgical Outcomes in Total Hip and Knee Replacement*, in 37 RECENT ADVANCES IN ARTHROPLASTY 35, 37 (Samo K. Fokter ed., 2012), <http://www.intechopen.com/books/recent-advances-in-arthroplasty/provider-volumes-and-surgical-outcomes-in-total-hip-and-knee-replacement> (reporting data for the 75% group); Jeffrey N. Katz et al., *Association Between Hospital and Surgeon Procedure Volume and the Outcomes of Total Knee Replacement*, 86 J. BONE & JOINT SURG. AM. 1909, 1909 (2004), <https://www.ncbi.nlm.nih.gov/pubmed/15342752> (reporting results data for the 25% group).

because the results likely do not represent the foreseeable application of the devices in the real world by the average surgeon.

b. Prejudicial Exclusion of Experience Testimony

Experience testimony is one of the few weapons in plaintiffs' arsenals, yet judges often unnecessarily and prejudicially disfavor experience testimony when little else is even possible in novel new device design cases.³¹¹ Most of the orthopaedic device makers are located in the small town of Warsaw, Indiana (population 13,559).³¹² Because industry design experts are unlikely to risk their careers by testifying against their benefactors, the plaintiff will generally be stuck choosing from the pool of experts who are not working in the orthopaedic implant industry.³¹³ Consequently, the plaintiff's experts will generally not have access to patients upon whom to perform randomized, controlled trials.³¹⁴ Nor will the plaintiff's experts generally have access to independent patient clinical follow-up data for the device at issue upon which to base his or her testimony (except in the rare instance where an overseas database is involved—like in the MoM hip cases).³¹⁵ The plaintiff's experts probably won't have an indexed population of patients who have undergone treatment with the device, or even a different device to compare. Thus, personal experience and research performed in preparation for the litigation may often be the sole basis for reliable expert testimony in these complex, novel cases.

The Rules do not disfavor experience witnesses. To the contrary, it is quite clear that experience is enough, because

311. See, e.g., *GTE Southwest, Inc. v. Bruce*, 998 S.W.2d 605, 620 (Tex. 1999) ("Where . . . the issue involves only . . . experience rather than expertise, it is within the province of the jury to decide, and admission of expert testimony . . . is error.").

312. Feder, *supra* note 205.

313. Cf. Phillip J. Kolczynski, *Ethical Challenges for Experts in Civil Litigation*, EXPERT PAGES, http://expertpages.com/news/ethical_challenges_for_experts_i.htm ("[A]n expert who changes sides on social or economic issues runs the risk of being 'black-listed' or 'black-balled' by the industry in which he previously worked.") (last visited Oct. 1, 2016).

314. See *id.*

315. See *id.*; NAT'L JOINT REGISTRY FOR ENG. AND WALES, cited in parenthetical *supra* note 109.

the 2000 amendment and Committee notes on Rule 702 specifically say:

Nothing in this amendment is intended to suggest that *experience alone*—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that *an expert may be qualified on the basis of experience*. In certain fields, experience is the *predominant, if not sole, basis* for a great deal of *reliable* expert testimony.³¹⁶

Thus, clearly the Rules contemplate cases like orthopaedic implant design cases where experience testimony might be the sole or predominant source of reliable expert testimony for a party.

Yet courts frequently exclude the operating surgeon's design defect opinions based on personal experience with the device and confine his or her testimony to treatment issues, saying the treating physician "may not offer an expert opinion, even one formed during the course of treatment . . ."³¹⁷ Board certified orthopaedic surgeons complete five years of specialized residency training and often an additional year of subspecialty fellowship training; thereafter, they continue to read the orthopaedic literature, take recertification examinations, and meet certification guidelines that require at least forty hours of continuing medical education annually attending meetings and listening to presentations where they often learn of the very devices at issue in the litigation.³¹⁸ If they are qualified to implant the device into human beings, they should be qualified to proffer opinions regarding the design features of the devices that they have personally used.

Further, the operating surgeon represents the foreseeable target user for the device's intended use, so his or her opinion is particularly relevant and reliable with regard to how the design functions in the hands of the end user. In contrast to the master surgeons who write the literature and are usually industry insiders, typical operating surgeons perform the majority of these procedures. Their expert observations are relevant and should be deemed reliable in determining design defects. Where the implant company blames the operating

316. FRE 702 Committee Notes, *supra* note 208 (emphasis added).

317. *Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 182 (E.D.N.Y. 2013).

318. *See, e.g.*, AM. BD. OF ORTHOPAEDIC SURGERY, *Maintenance of Certification*, <https://www.abos.org/moc.aspx> (last visited Nov. 9, 2016).

surgeon for the plaintiff's complications, the surgeon should especially be allowed to present his or her alternative theories of causation—including design defect.

In the bellwether Zimmer Flex knee case, the judge excluded experience testimony from two key plaintiff experts. First, she excluded the operating surgeon's testimony regarding design defect, even though the defendant's experts were allowed to blame the surgeon for causing the device failure by claiming he "hadn't properly secured the implants in place."³¹⁹ Thus, the jury only got to hear one side of the story directly from the parties involved—hearing the defendant's theory as to why the device failed (i.e., the surgeon did a bad job), but *not* the operating surgeon's theory (i.e., possibly, the device was defectively designed).³²⁰ Second, she barred experience testimony proffered by a well-qualified NYU orthopaedic professor who was performing over 100 total knees per year.³²¹ Amazingly, while barring experience testimony for the plaintiff, computer simulation testimony for the defense was allowed.³²² Overzealous exclusion of plaintiffs' experience experts likely has a chilling effect on just adjudication of orthopaedic design defect cases where plaintiffs must often rely on the testimony of personal experience experts using these novel devices.

3. Prejudicial Deference to Industry Polycentricity Arguments

Judges should neither accept industry arguments that design decisions are too complex for adjudication nor give special deference to the companies' design decisions. Instead, the companies' "substantial equivalence" decisions—which measure the leap from the last proven predicate to the device at issue—can serve as the measure of the amount of acceptable allowable latitude for plaintiff expert theories. Any argument

319. Sundar, *supra* note 180; *see also In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 3799534, at *9 (N.D. Ill. June 17, 2015) (precluding the doctor "from opining regarding the particular forces and stresses at work on the knee, the adequacy of Zimmer's testing, or whether the design of the knee caused Ms. Batty's loosening").

320. *See generally In re Zimmer*, 2015 WL 3799534.

321. *In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 3669933, at *19 (N.D. Ill. June 12, 2015).

322. *See In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 11-C-5468, 2015 WL 4880953 at *2–3 (N.D. Ill. Aug. 13, 2015); Baker, *supra* note 177.

that orthopaedic devices are “unavoidably unsafe” should also be summarily dismissed in today’s mature market, because many safe devices are already in use.

a. The Company’s “Substantial Equivalence” Decisions and “Predicate Chain” Should Serve as the Template for Adjudication of Reasonable Alternative Design Theories

Judges may be improperly influenced to defer to industry by commentators who conclude that the polycentric nature of design defect litigation involving medical devices “demands that the courts stay their hand and permit the manufacturer’s managerial safety decision to govern”—especially when it comes to plaintiffs offering reasonable alternative designs (RADs) of complex medical devices.³²³ One prominent author claims, “[t]he contention that this multifaceted and interconnected process is not fit for judicial determination is most persuasive when an alternative design suggested by the plaintiff would significantly alter the design of the product.”³²⁴ So manufacturers are likely to argue that design decisions are “polycentric” or “aspects of product design [are] related in such a way that any design change would substantially affect the cost, utility, [or] safety” of the device.³²⁵ At least one judge described prescription drug design defect cases as impossibly polycentric:

If one strand is pulled, a complex pattern of readjustments will occur throughout the entire web. If another strand is pulled, the relationships among all the strands will again be readjusted. A lawyer seeking to base [an] argument upon established principle and required to address himself in discourse to each of a dozen strands, or issues, would find [the] task frustratingly impossible.³²⁶

However, the same author notes that “[e]ven though polycentric problems are not suited to adjudication, it does not follow that they are incapable of rational resolution.”³²⁷ One

323. Aaron D. Twerski, *From Risk-Utility to Consumer Expectation: Enhancing the Role of Judicial Screening in Product Liability Litigation*, 11 HOFSTRA L. REV. 861, 867 (1983); see also James A. Henderson Jr., *Judicial Review of Manufacturers’ Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531 (1973).

324. Twerski, *supra* note 323, at 891.

325. Twerski, *supra* note 188, at 527.

326. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98 (Utah 1991) (quoting Henderson, *supra* note 323) (editing in original).

327. Henderson, *supra* note 323, at 1538.

court noted, “[l]aw lags science; it does not lead it.”³²⁸ However, law can surely try to distinguish “science” from marketing.

Fortunately for the judge in an orthopaedic implant design case, the defendant has supplied a map for rational resolution of RAD polycentricity questions—the liberties taken during the FDA approval process, and the differences between the device at issue and its “predicate device” used by the company to meet “substantial equivalence” standards. The product’s “predicate chain” (the series of leaps from predicate to predicate upon which the device obtained FDA clearance) should serve as the template for judges to determine how much flexibility to give plaintiffs’ experts in proffering RADs and offering speculative testimony.

If the product’s “substantially equivalent” predicate is a very close approximation of the device in question *and* the predicate has a proven track record for safety and efficacy, then the plaintiff’s expert should be allowed little latitude. However, if the device at question takes a speculative leap of faith from the predicate device based on only theories, *or* if the predicate device is unproven (or worse, failed), then the plaintiff’s expert should be given plenty of flexibility to proffer similar speculative theories and leaps of faith. As one jurist noted, “[t]he courtroom is not the place for scientific guesswork, even of the inspired sort”³²⁹—a maxim that applies equally to defendants who base design decisions on “inspired” guesswork leaps from weak predicate foundations when taking the FDA’s “substantial equivalence” shortcut. For example, the ASR MoM hip system was reportedly cleared by the FDA based on three predicate devices originating prior to 1976—including the McKee-Farrar, Ring, and Sivash MoM hip implants—all of which were reportedly removed from the market due to high revision rates.³³⁰ In this case, if the device’s “predicate chain” is based on devices with high failure rates, then plaintiffs’ experts should be given significant, reasonable latitude in proposing RADs and other design defect theories.

328. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).

329. *Id.*

330. Bruera, *supra* note 76, at 36; *see also* Ardaugh et al., *supra* note 106.

b. Where “Good” Alternatives Already Exist, the Argument that Medical Devices are “Unavoidably Unsafe” Should Be Summarily Dismissed

Device manufacturers should fail in their arguments that their wares are “unavoidably unsafe” where they have taken the “substantial equivalence” shortcut, and especially where there are safe alternatives already on the market. Comment k of § 402A of the Restatement (Second) of Torts defines “unavoidably unsafe products” as “some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.”³³¹ Comment k specifically mentions “drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician.”³³² Comment k goes on to note that the seller of such products “is not to be held to strict liability.”³³³

Orthopaedic device manufacturers have tried to extend the immunity given drugs to medical devices—downplaying the vast differences in the FDA approval processes between drugs and medical devices.³³⁴ Where a drug is approved after three sets of clinical trials, the argument that it is “unavoidably unsafe” may have merit. But, where a medical device is cleared after only twenty hours³³⁵ of paperwork declaring “substantial equivalence” to a predicate that may have even failed, there simply has not been enough testing to argue with any merit that the device is unavoidably unsafe. There may have been no significant effort made to make it safe in the first place since the effort may have been only to declare it “substantially equivalent.”

A Pennsylvania court actually bought the “unavoidably unsafe” argument with regard to total knee replacement tibial

331. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (AM. LAW INST. 1965).

332. *Id.*

333. *Id.*

334. Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. TIMES (Feb. 21, 2008) <http://www.nytimes.com/2008/02/21/washington/21device.html> (“Makers of medical devices like implantable defibrillators or breast implants are immune from liability for personal injuries as long as the Food and Drug Administration approved the device before it was marketed and it meets the agency’s specifications.”).

335. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (noting that the 510(k) notification process is “completed in an average of only twenty hours”).

inserts, and ruled that prescription medical devices were “unavoidably unsafe” such that manufacturers of medical devices are “effectively immune from strict liability suit in Pennsylvania.”³³⁶ The logic was based on the idea that there was “no reason why the same [‘unavoidably unsafe’] rational[e] applicable to prescription drugs may not be applied to medical devices”—evidently failing to recognize the vast differences in the FDA approval process for drugs versus medical devices.³³⁷ If a device company takes the device through the premarket approval process (PMA) which more closely approximates the FDA clearance method used for drugs, then state law causes of action are already likely preempted by federal law³³⁸—so the company can choose the PMA pathway and get even better liability protection than Comment k. However, if the company chooses the “substantial equivalence” pathway, they likely have not put forth enough effort to declare the lack of safety “unavoidable.”

At least one orthopaedic device manufacturer argued in a MoM hip case that holding the company strictly liable under products liability law would “contradict the strong public policy encouraging developments in medical treatment,” noting that Texas has recognized Comment k for prescription drugs, and should do so for medical devices.³³⁹ The Plaintiff wisely pointed out that the FDA approval process for prescription drugs is “drastically different” from the FDA’s 510(k) process.³⁴⁰ The case survived summary judgment, but the court did not exclude the possibility of applying Comment k at a later stage of the proceedings.³⁴¹

The idea that hip replacements are “unavoidably unsafe,” given the long term success of Charnley’s hips and other metal

336. *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 749 (E.D. Pa. 2007).

337. *Id.* at 750.

338. *See Lohr*, 518 U.S. at 470 (invoking the preemption provisions of 21 U.S.C. § 360k(a) (2012), which prevent supplementation or contradiction of federal law relating to safety or effectiveness of medical devices); *Reigel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (similar preemption discussion).

339. *Anastasi v. Wright Med. Tech., Inc.*, 16 F. Supp. 3d 1032, 1040 (E.D. Mo. 2014).

340. *Id.*

341. *Id.* at 1041 (“The Court finds Defendants’ Comment k argument is prematurely brought in their Motion to Dismiss.”).

on polyethylene models, is far-fetched.³⁴² Most jurisdictions rule that only if the products' benefits exceed its risks *and* it is incapable of being made safer are Comment k's protections available.³⁴³ Total hips are clearly being made safely and have many years of proven safety records.³⁴⁴ Orthopaedic devices approved by the 510(k) approval process and those in categories where there are already safe devices should not be declared "unavoidably unsafe."

IV. JUDGES SHOULD CORRECT PREJUDICIAL *DAUBERT* TENDENCIES FAVORING DEFENDANTS IN ORTHOPAEDIC DESIGN DEFECT CASES AS A MATTER OF PUBLIC POLICY

Unproven "substantially equivalent" devices often offer society nothing more than higher costs with no improvement in outcomes over existing devices in mature orthopaedic implant markets, and sometimes these devices lead to unnecessary, costly complications.³⁴⁵ Device manufacturers often blame the operating surgeon for the failures.³⁴⁶ This may lead to tendencies for the legal system to shift the burden for unproven devices onto the medical malpractice system and the healthcare system as a whole, because lawyers may choose to pursue less complex and more common medical malpractice claims over very complex design defect claims in an unfavorable *Daubert* environment.³⁴⁷ As a public policy matter, implant companies are in a much better position than surgeons, patients, and the general public to reduce the hazards inherent in their unproven devices; the manufacturer can choose better premarket testing,

342. See, e.g., Neumann et al., *supra* note 2; Caton et al., *supra* note 85; Callaghan et al., *supra* note 86, at 2617–21.

343. See DAVID G. OWEN & MARY J. DAVIS, 2 OWEN & DAVIS ON PRODUCTS LIABILITY § 19:5 (4th ed. 2014).

344. See, e.g., Neumann et al., *supra* note 2; Caton et al., *supra* note 85; Callaghan et al., *supra* note 86, at 2617–21.

345. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996) (defining the 501(k) process as allowing an alternative to the PMA process for devices "substantially equivalent" to devices already on the market).

346. See, e.g., Meier, *supra* note 154 (Dr. Berger blamed); Meier, *supra* note 240 (reporting that Dr. Dorr was the victim of a "whisper campaign").

347. In 2010, medical malpractice costs totaled approximately \$29.8 billion in the United States. See WILLIS TOWERS WATSON, 2011 UPDATE ON U.S. TORT COST TRENDS 10, 17 (January 2012), <https://www.towerswatson.com/en-US/Insights/IC-Types/Survey-Research-Results/2012/01/2011-Update-on-US-Tort-Cost-Trends> (providing a link to a downloadable PDF report).

use the PMA approval process as a federal preemption shield, and perform postmarket surveillance on its devices.

A. IMPLANT COMPANIES' BLAME SHIFTING TO OPERATING SURGEONS MAY INFLUENCE ATTORNEYS TO CHOOSE MEDICAL MALPRACTICE CLAIMS OVER MORE COMPLEX DESIGN DEFECT CLAIMS IN AN UNFAVORABLE *DAUBERT* ENVIRONMENT

As evidenced above, implant companies generally have no qualms with throwing operating surgeons to the wolves when it comes to assigning blame for the failure of medical devices.³⁴⁸ Even their most decorated, loyal surgeons are fair fodder to be sacrificed to the courts.³⁴⁹ For design defects that cause early failures within the medical malpractice statute of limitations, physicians' malpractice policies are a more viable target for plaintiffs' lawyers than complex design defect cases.³⁵⁰

Even the most ardent industry insiders and consultants are blamed for device failures by the companies. Remember, Dr. Richard Berger in the Zimmer Flex case went from being a company star with "clever . . . hands" and a "master teacher" to "someone who didn't know what he was doing" when he reported early concerns with a device.³⁵¹ Dr. Lawrence Dorr had a similar experience when he alerted Zimmer about bad outcomes with one of its total hip sockets (i.e., the Durom® acetabular cup).³⁵² According to his website, Dr. Dorr "has performed more than 3,500 hip and knee replacements in the past decade" and is the president of the Hip Society—a prestigious organization of hip surgeons consisting of the top 100 hip surgeons in the world.³⁵³ Dr. Dorr founded the "Masters Series" meetings to educate orthopaedic surgeons while he was a professor at the University of Southern California with the backing of multiple device manufacturers (including Zimmer, DePuy, Stryker, Smith & Nephew, and

348. See, e.g., *supra* note 346.

349. *Id.*

350. See, e.g., WILLIS TOWERS WATSON, *supra* note 347.

351. Meier, *supra* note 154.

352. See Lawrence Dorr, *Memo to the American Association of Hip and Knee Surgeons*, SURFACE HIPPO (Apr. 22, 2008), <http://surfacehippy.info/dr-dorr-memo-to-american-association-of-hip-and-knee-surgeons-about-the-durom-cup-by-zimmer/>; Meier, *supra* note 240.

353. DORR ARTHRITIS INST., *Dr. Lawrence Dorr*, [http:// www.dorrarthritisinstitute.org/dorr.html](http://www.dorrarthritisinstitute.org/dorr.html) (last visited Sept. 7, 2016).

Biomet).³⁵⁴ He has been designing hip and knee implants since 1982 and has been paid “millions of dollars” in royalties for his devices.³⁵⁵

In 2008, Dr. Dorr warned other orthopaedic surgeons in an open letter to the American Association of Hip and Knee Surgeons that his patients were experiencing what he apparently considered an unusual number (14 of 165 hips) of revisions or impending revisions with the company’s hip socket within the first two years after surgery.³⁵⁶ After the letter, Dr. Dorr became the subject of a “whisper campaign [questioning] his skills as a surgeon.”³⁵⁷ Dr. Dorr says that when a surgeon reports a problem with a device, “[t]he first thing that a company does is to put out a campaign that a surgeon does not know how to operate” noting that the smear campaign “hurt [his] practice for a year.”³⁵⁸ Dr. Dorr said the company told him no other surgeons were having any problems.³⁵⁹ Two prominent surgeons eventually came to Dr. Dorr’s defense noting similar issues, but the damage was already done to Dr. Dorr’s practice.³⁶⁰

Since they willingly blame their “master” surgeons, it should come as no surprise that implant companies often blame other operating surgeons for device failures—sometimes perhaps rightfully, but sometimes likely wrongfully based upon Dorr’s experience. In the recent DePuy Pinnacle MoM case, the company blamed the operating surgeon, saying the hip implant was “improperly positioned.”³⁶¹ Likewise, in the bellwether Zimmer Flex knee case, Zimmer blamed the operating surgeon saying he “hadn’t properly secured the implants in place.”³⁶² In those two cases, the jury decided whether to believe the company’s blame-shifting, but the ease and frequency of blame-shifting in these products liability cases may convince many

354. *Id.*

355. *Id.*

356. Dorr, *supra* note 352.

357. Meier, *supra* note 240.

358. *Id.*

359. See Meier, *supra* note 154 (stating that Zimmer asserted “the problem was [instead with] Dr. Dorr’s technique”).

360. *Id.*

361. *Johnson & Johnson’s DePuy Wins First Trial over Pinnacle Hips: Herlihy-Paoli v. DePuy Orthopaedics*, *supra* note 120, at 1.

362. Sundar, *supra* note 180.

plaintiff's lawyers to pursue medical malpractice cases against surgeons instead of products liability cases against device makers.

Surgeons (and hospitals³⁶³) may thus be bearing much of the financial burden of inadequately tested medical devices through blame-shifting tactics by the medical device industry that encourage plaintiffs' lawyers to go after doctors and hospitals with medical malpractice claims, instead of device manufacturers with products liability complaints.

B. FROM A PUBLIC POLICY PERSPECTIVE, IMPLANT MANUFACTURERS ARE IN THE BEST POSITION TO REDUCE THE HAZARDS ASSOCIATED WITH UNPROVEN ORTHOPAEDIC DEVICES AND TO MANAGE THE ASSOCIATED COSTS

"[P]ublic policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market."³⁶⁴ Implant companies are in the best position as a matter of public policy to manage the risks and costs associated with releasing unproven orthopaedic devices into the market: the manufacturer has the opportunity to choose better premarket testing, to use the PMA approval process as a federal preemption shield, and to perform postmarket surveillance on its devices.³⁶⁵

First, better premarket testing is an option available to implant companies that is not available to surgeons, patients, or the general public. For medical devices in particular, "manufacturer[s] can anticipate some hazards and guard against the recurrence of others, as the public cannot."³⁶⁶ The public is helpless to detect hidden design defects in devices that have been inadequately tested or based upon faulty predicate

363. *E.g.*, *Harrison v. Slidell Specialty Hosp.*, No. 2013 CA 0691, 2013 WL 6858261 (La. Ct. App. 2013), *writ denied*, 138 So.3d 606 (La. 2014) at 7–8 (holding that a plaintiff can bring a cause of action against the hospital in which the faulty device was implanted).

364. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440–41 (Cal. 1944).

365. *Cf.* IOM REPORT, *supra* note 69, at 5–11 (describing the PMA and 501(k) processes, and recommendations for the industry that include postmarket surveillance); *id.* at 137–42 (discussing non-FDA postmarket surveillance).

366. *Escola*, 150 P.2d at 440–41.

devices.³⁶⁷ When 88% percent of orthopaedic devices are reaching the market via the 510(k) shortcut versus only 53% of other medical devices, orthopaedic device manufacturers are apparently making conscious decisions to put the public at unnecessary risk of injury, knowing there is a markedly higher risk of device recall (11.5 times) and injury than if they did premarket trials and obtained clearance through the PMA process.³⁶⁸

The lack of premarket testing is particularly disturbing when there are already safe and effective devices on the market. Market deterrence theory dictates that manufacturers who use marketing ploys, instead of scientific testing, to create demand for risky products should pay the price when the devices fail.³⁶⁹ Public health and well-being is promoted by discouraging “the marketing of products having defects that are a menace to the public.”³⁷⁰ Companies that replace effective devices with ineffective, more expensive, and riskier devices are particularly menacing to the public and should foot the bill for the failures.³⁷¹

Second, orthopaedic device manufacturers can choose federal preemption to insure against design defect liability risks by choosing the PMA pathway to FDA clearance, instead of 510(k) and “substantial equivalence.”³⁷² Fewer device recalls (11.5 times fewer) under the PMA pathway will lead to lower costs of healthcare associated with the recalled devices and likely lower cost of malpractice cases against surgeons.³⁷³ If healthcare costs of complications and malpractice are reduced, the system may be able to pay enough to offset the added cost

367. *Id.*

368. Day et al., *supra* note 65, at 517.

369. See generally James A. Henderson, Jr., *Coping with the Time Dimension in Products Liability*, 69 CAL. L. REV. 919, 931–39 (1981) (discussing the “Traditional Justifications for Strict Products Liability”).

370. *Escola*, 150 P.2d at 441.

371. Cf. Freeman, *supra* note 75, at 139 (“The unknown risks that Class III devices pose when they are cleared with inadequate predicates is an unethical burden that patients should not have to bear.”).

372. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996) (invoking the preemption provisions of 21 U.S.C. § 360k(a), which prevent supplementation or contradiction of federal law relating to safety or effectiveness of medical devices); *Reigel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (similar preemption discussion).

373. See Day et al., *supra* note 65, at 517.

to the company of the premarket testing involved in the PMA process.³⁷⁴

Thus, the PMA process may spread the cost of injuries over all users of the devices so that the companies' research and development costs "can be insured by the manufacturer and distributed among the public as a cost of doing business."³⁷⁵ Otherwise, in an unfavorable *Daubert* environment, "[t]he cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured."³⁷⁶ Further, if the devices are cleared by the PMA process, society in the future may truly be talking about the "cutting edge" of orthopaedics instead of the "marketing edge" of big business—so going forward the public may benefit from true scientific advancement instead of shiny, new implants in velvet boxes hawked by salesmen instead of scientists.

Finally, postmarket surveillance of medical devices was recommended by the Institute of Medicine as part of the replacement of the 510(k) process.³⁷⁷ One example of postmarket surveillance—total joint registries—has been around in other countries for years,³⁷⁸ and is finally beginning in the United States.³⁷⁹ The U.K. and Australian joint registries played a major role in detecting the problems associated with metal-on-metal hips.³⁸⁰ Postmarket surveillance of all new orthopaedic devices should be implemented as recommended by the IOM, and joint registries can serve as a model for implementation. In addition to detecting problems early, companies stand to benefit by improving future designs where doctor and patient feedback can be factored into future design changes.

374. See generally WILLIS TOWERS WATSON, *supra* note 347 (noting that medical malpractice costs in 2010 were nearly \$30 billion).

375. *Escola*, 150 P.2d at 441.

376. *Id.*; see, e.g., *In re Wagner*, 530 B.R. 695, 697 (E.D. Wis. 2015) (describing the debtor as suffering from a failed hip surgery, which debtor blamed for her bankruptcy).

377. IOM REPORT, *supra* note 69, at 9–10.

378. David Ayers & Patricia Franklin, *Joint Replacement Registries in the United States: A New Paradigm*, 96 J. BONE & JOINT SURGERY AM. 1567, 1568 (2014), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159967/>.

379. *Id.*; see *Improving Orthopaedic Care Through Data*, AM. JOINT REPLACEMENT REG., <http://www.ajrr.net> (last visited Oct. 13, 2016).

380. See Ardaugh et al., *supra* note 106, at 98.

V. CONCLUSION

Orthopaedic medical devices have improved the health of countless Americans. However, device companies cause unnecessary harm to patients when they put marketing ahead of science, leaving behind proven devices for unproven speculative marketing schemes. Orthopaedic surgery patients are particularly vulnerable because there are multiple signs that industry may be the “tail” wagging the proverbial medicine “dog”—including signs of corruption (e.g., fines, settlements, prison), “striking” unexplainable shifts in device use, and disproportionate use of the “substantial equivalence” pathway to device clearance.

Expert testimony is vital in orthopaedic design cases. A close look at some recent orthopaedic design cases supports the idea that judges are being too deferential in admitting defense experts while being overzealous in excluding plaintiffs’ experts. The prejudicial *Daubert* rulings appear to be related to judges overestimating the reliability of orthopaedic epidemiology studies and of experts with million dollar conflicts of interest, while simultaneously underestimating the reliability of novel research performed in preparation for trial and of experts who testify based on personal experience. In addition, judges may ignore device industry polycentricity issues created by the “substantial equivalence” determination while deferring to industry on polycentricity grounds when analyzing plaintiffs’ design theories.

The end result of the current system is that orthopaedic implant companies are making an economic business decision to release their devices using only “substantial equivalence” to gain clearance at a markedly higher rate than other medical devices (88%, vs. 53%)—choosing to simply absorb the current litigation costs associated with the 11.5 times higher device recall rate.³⁸¹ The economic calculus needs to change in order to encourage more investment in device safety and efficacy prior to release. The orthopaedic implant industry is in the best position to reduce the hazards associated with unproven medical devices, through use of premarket testing, by utilizing federal preemption protection through the PMA pathway, and through postmarket surveillance. When surgeons take the blame, higher malpractice premiums may add to the financial

381. Day et al., *supra* note 65, at 517.

burdens of the health care system. When patients have more complications related to recalled devices, the public and patients pay more through higher healthcare costs, and through lost wages and poor health.

In many ways, the current prejudicial *Daubert* approach favoring industry facilitates a kind of “bodily eminent domain”³⁸² claim, by which the orthopaedic implant industry feels entitled to the “taking” of Americans’ health in the name of profits. Judges can do a better job in providing for just adjudication of complex orthopaedic design defect cases by understanding and accounting for the issues discussed in this paper.

382. GAWANDE, *supra* note 7.